

US3302327 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:12:12

All time stamps listed in this document are displayed in GMT

US3302327

**Form: Participant Creation**

**Data signed:** (b) (4) 19 Feb 2021 19:14:19

**Generated On:** 11 Aug 2021 22:12:12

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[Participant ID](#)

US3302327

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

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US3302327

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 21 AUG 2020

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

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Folder OID SCRN

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US3302327

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	33
Age Units	YEARS
Age (Derived)	33
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) 19 Feb 2021 19:14:20

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Date of Informed Consent (*dd MMM yyyy*) 21 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:14:20

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:14:20

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:51 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:51
Height ( <i>xxx.x</i> )	70 in
Weight ( <i>xxx.x</i> )	145 lb
BMI ( <i>xxx.x</i> )	20.84884 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) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

21 AUG 2020

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*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) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

Date of assessment (*dd MMM yyyy*) 21 AUG 2020

Is the participant of childbearing potential? Yes   
No

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

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

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

Was the pregnancy test performed? Yes   
No

Date of test (dd MMM yyyy) 21 AUG 2020

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:14:20

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

---

**Specify**

---

**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) 19 Feb 2021 19:14:20

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 21 AUG 2020

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

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Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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

What was the participant's randomization number? 107219

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) 19 Feb 2021 19:14:20

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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)	21 AUG 2020
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 14:51
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:09 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 16:09
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	73 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Was the physical examination performed?

Yes

No

---

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

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*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) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:39 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 15:39

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) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 21 AUG 2020

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Collection time (*00:00-23:59*) 15:04 (24 HR)

---

Collection date and time (derived) 21 AUG 2020 15:04

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Collection date ( <i>dd MMM yyyy</i> )			21 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:01	21 AUG 2020 15:01
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**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 98.2 °F

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

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

PC Time Stamp 21 AUG 2020 15:59

PC Open Date & Time 21 AUG 2020 15:59

PC Close Date & Time 21 AUG 2020 18:29

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.7 °F

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

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

PC Time Stamp	22 AUG 2020 08:41
PC Open Date & Time	21 AUG 2020 19:24
PC Close Date & Time	22 AUG 2020 11:59

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 AUG 2020 09:35
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 AUG 2020 07:42
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.7 °F

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

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

PC Time Stamp 25 AUG 2020 07:49

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp 26 AUG 2020 07:32

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 AUG 2020 08:14
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 AUG 2020 08:00
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**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

Please record - **REDNESS AT INJECTION SITE (in mm)**

1

Measure the largest size across any injection site redness with the ruler provided.

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.**

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity
- Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

21 AUG 2020 16:01

PC Open Date & Time

21 AUG 2020 15:59

PC Close Date & Time

21 AUG 2020 18:29

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**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 - **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.**

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 22 AUG 2020 08:42

PC Open Date & Time 21 AUG 2020 19:24

PC Close Date & Time 22 AUG 2020 11:59

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 2

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

23 AUG 2020 09:36

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 3

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

24 AUG 2020 07:43

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 4

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

25 AUG 2020 07:50

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 5

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	26 AUG 2020 07:32
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 6

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

27 AUG 2020 08:15

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 7

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

28 AUG 2020 08:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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

No

Yes

---

PC Time stamp	21 AUG 2020 16:01
PC Open Date & Time	21 AUG 2020 15:59
PC Close Date & Time	21 AUG 2020 18:29

---

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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

No   
Yes

---

PC Time stamp	22 AUG 2020 08:43
PC Open Date & Time	21 AUG 2020 19:24
PC Close Date & Time	22 AUG 2020 11:59

---

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 09:36
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

---

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 07:43
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

---



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 07:50
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

---

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	26 AUG 2020 07:33
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

---

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	27 AUG 2020 08:15
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

---

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 08:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

---



US3302327

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3302327

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 7 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3302327

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3302327

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

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US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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 ( <i>dd MMM yyyy</i> )	18 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:35 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:35
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	79 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG



US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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 ( <i>dd MMM yyyy</i> )	18 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:25 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:25
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG

US3302327

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

18 SEP 2020

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

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US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

Was the pregnancy test performed? Yes   
No

Date of test (dd MMM yyyy) 18 SEP 2020

Test performed Urine   
Serum

Result Positive   
Negative

Was FSH sample collected? Yes   
No

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

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 13:55 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 13:55

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

US3302327

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 18 SEP 2020

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Collection time (*00:00-23:59*) 13:43 (24 HR)

---

Collection date and time (derived) 18 SEP 2020 13:43

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US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Collection date ( <i>dd MMM yyyy</i> )			18 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:41	18 SEP 2020 13:41
Nasopharyngeal Swab 2	No		

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US3302327

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**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 98.7 °F

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

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

PC Time Stamp 18 SEP 2020 14:15

PC Open Date & Time 18 SEP 2020 14:15

PC Close Date & Time 18 SEP 2020 16:45



US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.8 °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 19 SEP 2020 07:26  
PC Open Date & Time 18 SEP 2020 17:40  
PC Close Date & Time 19 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**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** 96.8 °F

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

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

PC Time Stamp 20 SEP 2020 00:03

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 18:13
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.4 °F

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

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

PC Time Stamp 21 SEP 2020 22:42

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 07:42
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 22:06
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 SEP 2020 08:00
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**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

18 SEP 2020 14:16

PC Open Date & Time

18 SEP 2020 14:15

PC Close Date & Time

18 SEP 2020 16:45



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**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

19 SEP 2020 07:26

PC Open Date & Time

18 SEP 2020 17:40

PC Close Date & Time

19 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 2

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	20 SEP 2020 00:04
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 3

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

20 SEP 2020 18:13

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

21 SEP 2020 22:42

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 5

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

23 SEP 2020 07:42

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 6

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

23 SEP 2020 22:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 7

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

25 SEP 2020 08:01

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**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



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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

No

Yes

---

PC Time stamp	18 SEP 2020 14:16
PC Open Date & Time	18 SEP 2020 14:15
PC Close Date & Time	18 SEP 2020 16:45

---

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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

No

Yes

---

PC Time stamp	19 SEP 2020 07:26
PC Open Date & Time	18 SEP 2020 17:40
PC Close Date & Time	19 SEP 2020 11:59

---

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 00:04
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

---

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 18:14
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

---

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**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



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	21 SEP 2020 22:43
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

---

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 07:43
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

---

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	23 SEP 2020 22:06
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

---

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

---

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 08:01
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

---

US3302327

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---



US3302327

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3302327

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3302327

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

---

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	08:20 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 08:20
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	85 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302327

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

19 OCT 2020

---

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

---



US3302327

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Was the sample collected? Yes   
No

---

Collection date (*dd MMM yyyy*) 19 OCT 2020

---

Collection time (*00:00-23:59*) 08:22 (24 HR)

---

Collection date and time (derived) 19 OCT 2020 08:22

---

US3302327

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 08:02:01
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission 28 OCT 2020 08:52:15

Patient Cloud Open Date & Time 28 OCT 2020 00:01

Patient Cloud Close Date & Time 01 NOV 2020 23:59

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 05 NOV 2020 00:10:13

Patient Cloud Open Date & Time 04 NOV 2020 00:01

Patient Cloud Close Date & Time 08 NOV 2020 23:59

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 92

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

No

Yes

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

No

Yes

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

Date and time of submission 18 NOV 2020 08:27:01

Patient Cloud Open Date & Time 18 NOV 2020 00:01

Patient Cloud Close Date & Time 22 NOV 2020 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 09:39:15
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 29 NOV 2020 09:28:37

Patient Cloud Open Date & Time 29 NOV 2020 00:01

Patient Cloud Close Date & Time 03 DEC 2020 23:59



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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	06 DEC 2020 07:47:15
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 09:17:03
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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	20 DEC 2020 09:52:32
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 131

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

No

Yes

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

No

Yes

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

Date and time of submission 28 DEC 2020 12:48:37

Patient Cloud Open Date & Time 27 DEC 2020 00:01

Patient Cloud Close Date & Time 31 DEC 2020 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

03 JAN 2021 10:54:09

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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 10 JAN 2021 08:31:35

Patient Cloud Open Date & Time 10 JAN 2021 00:01

Patient Cloud Close Date & Time 14 JAN 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 12:38:21
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 24 JAN 2021 00:01:30

Patient Cloud Open Date & Time 24 JAN 2021 00:01

Patient Cloud Close Date & Time 28 JAN 2021 23:59



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

<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	31 JAN 2021 07:28:02
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 <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	07 FEB 2021 08:27:58
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 FEB 2021 09:06:03
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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 22 FEB 2021 11:38:19

Patient Cloud Open Date & Time 21 FEB 2021 00:01

Patient Cloud Close Date & Time 25 FEB 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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	28 FEB 2021 13:10:58
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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	07 MAR 2021 08:44:31
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 15:28:48
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 08:53:07
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 08:49:15
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 <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	05 APR 2021 08:14:36
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	11 APR 2021 07:32:02
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 APR 2021 08:07:21
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 07:29:35
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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 <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	02 MAY 2021 07:08:30
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 264

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 271

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 285

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 320

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

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15 JUL 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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18 JUL 2021 00:01

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22 JUL 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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  Yes

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

US3302327

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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  Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 AUG 2021 00:01

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12 AUG 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

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19 AUG 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

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26 AUG 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

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02 SEP 2021 23:59



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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) \_\_\_\_\_

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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 \_\_\_\_\_

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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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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09 SEP 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 390

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

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

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

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

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

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- Shortness of breath \_\_\_\_\_
- Difficulty breathing \_\_\_\_\_
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- Muscle aches \_\_\_\_\_
- Body aches \_\_\_\_\_
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- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

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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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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16 SEP 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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):

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- Cough \_\_\_\_\_
- Shortness of breath \_\_\_\_\_
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- Body aches \_\_\_\_\_
- Headache \_\_\_\_\_
- New loss of taste \_\_\_\_\_
- New loss of smell \_\_\_\_\_
- Sore throat \_\_\_\_\_
- Congestion \_\_\_\_\_
- Runny nose \_\_\_\_\_
- Nausea \_\_\_\_\_
- Vomiting \_\_\_\_\_
- Diarrhea \_\_\_\_\_

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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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 404

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#) 30 SEP 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 411

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 24 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 28 OCT 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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   
Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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   
Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#) 18 NOV 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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  Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 467

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 488

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 26 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 30 DEC 2021 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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13 JAN 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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16 JAN 2022 00:01

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20 JAN 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

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**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 530

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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10 FEB 2022 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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17 FEB 2022 23:59



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

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03 MAR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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10 MAR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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°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

US3302327

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

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**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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07 APR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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   
Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

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14 APR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 607

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

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21 APR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 621

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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02 JUN 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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09 JUN 2022 23:59



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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  Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 684

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3302327

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

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**Generated On: 11 Aug 2021 22:12:12**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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07 JUL 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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  Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

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

Date and time of submission

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24 JUL 2022 00:01

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28 JUL 2022 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 712

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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04 AUG 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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  Yes

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

US3302327

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

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**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

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11 AUG 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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   
Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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18 AUG 2022 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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   
Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

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01 SEP 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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04 SEP 2022 00:01

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08 SEP 2022 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 18 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#) 22 SEP 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 768

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

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US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**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   
Yes

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

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

---

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

---

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

---



US3302327

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:12:12

---

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 13:11:16

---

US3302327

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3302327

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3302327

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 13 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3302327

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 FEB 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---



US3302327

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:20:52

Generated On: 11 Aug 2021 22:12:12

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 23 MAR 2021

---

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

---

Folder OID VISIT4

---

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 16:01:36

Generated On: 11 Aug 2021 22:12:12

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) 23 MAR 2021

Time of assessment (00:00-23:59) 08:40 (24 HR)

Vital Signs Date and Time (derived) 23 MAR 2021 08:40

Temperature (xxx.x) 97.5 F

Route of measurement Oral   
Axillary   
Other

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) 108 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 71 mmHg

Diastolic Blood Pressure units MMHG

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

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

US3302327

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:20:52

Generated On: 11 Aug 2021 22:12:12

---

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.*

---

US3302327

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:20:52

Generated On: 11 Aug 2021 22:12:12

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 23 MAR 2021

---

Collection time (*00:00-23:59*) 08:44 (24 HR)

---

Collection date and time (derived) 23 MAR 2021 08:44

---

US3302327

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:20:52

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 12:34:05

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 13 APR 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3302327

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 12:34:05

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3302327

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

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* \_\_\_\_\_

US3302327

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3302327

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:12:12

---

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"/>

---

US3302327

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:12:12

---

Generate Next COVID-19 Assessment

Yes

No

---

US3302327

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 26 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3302327

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 12:34:05

Generated On: 11 Aug 2021 22:12:12

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3302327

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Height	_____
Weight	_____
BMI (xxx.x)	_____

---

US3302327

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

Height	_____
Weight	_____
BMI (xxx.x)	_____
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 09:07
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG



US3302327

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

Height	_____
Weight	_____
BMI (xxx.x)	_____
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 09:55
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3302327

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

26 JAN 2021

---

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

---

US3302327

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

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

Was the pregnancy test performed? Yes   
No

Date of test (dd MMM yyyy) 26 JAN 2021

Test performed Urine   
Serum

Result Positive   
Negative

Was FSH sample collected? Yes   
No

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

US3302327

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 09:10 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 09:10

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

US3302327

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 26 JAN 2021

---

Collection time (*00:00-23:59*) 08:50 (24 HR)

---

Collection date and time (derived) 26 JAN 2021 08:50

---

US3302327

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 26 JAN 2021

---

Collection time (*00:00 - 23:59*) 08:48

---

Collection Date and Time (derived) 26 JAN 2021 08:48

---

US3302327

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3302327

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---



US3302327

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:14:20

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

---

US3302327

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 18:57:47

Generated On: 11 Aug 2021 22:12:12

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

---

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 18:57:47

Generated On: 11 Aug 2021 22:12:12

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 ( <i>dd MMM yyyy</i> )	26 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	09:35 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 09:35
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	83 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	66 mmHg
Diastolic Blood Pressure units	MMHG

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 18:57:47

Generated On: 11 Aug 2021 22:12:12

Timepoint Pre-Dose   
Post-Dose

Were vital signs assessed? Yes   
No

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

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

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

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

Route of measurement Oral   
Axillary   
Other

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

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

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

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

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

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

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

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

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

US3302327

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 18:57:47

Generated On: 11 Aug 2021 22:12:12

---

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.*

---

US3302327

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 25 Mar 2021 18:20:51

Generated On: 11 Aug 2021 22:12:12

Was the pregnancy test performed? Yes   
No

Date of test (dd MMM yyyy) 26 FEB 2021

Test performed Urine   
Serum

Result Positive   
Negative

Was FSH sample collected? Yes   
No

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

US3302327

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 18:57:47

Generated On: 11 Aug 2021 22:12:12

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? (Unblinded) \_\_\_\_\_

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? \_\_\_\_\_

US3302327

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 18:57:47

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3302327

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:43:29

Generated On: 11 Aug 2021 22:12:12

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 MAR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3302327

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:20:52

Generated On: 11 Aug 2021 22:12:12

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

---

US3302327

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:20:51

Generated On: 11 Aug 2021 22:12:12

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 23 MAR 2021

---

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

---

Folder OID OLD57

---

US3302327

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 18:20:51

Generated On: 11 Aug 2021 22:12:12

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:40 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 08:40
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	88 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3302327

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:20:51

Generated On: 11 Aug 2021 22:12:12

---

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.*

---

US3302327

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:20:51

Generated On: 11 Aug 2021 22:12:12

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 23 MAR 2021

---

Collection time (*00:00-23:59*) 08:44 (24 HR)

---

Collection date and time (derived) 23 MAR 2021 08:44

---

US3302327

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3302327

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

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

Yes

No

---

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

---



US3302327

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:14:19

Generated On: 11 Aug 2021 22:12:12

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3302327

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:12:12

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

US3302327 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

US3302327

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:12:12**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User closed query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:45:34
Query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' answered with 'updated' (Site from CRA).	brittany cooksey (b) (4) (b) (4)	19 Nov 2020 15:05:44
User opened query 'Please complete the AE Summary Page. Per source, no AEs have occurred yet. You can answer the page and change the answer if an AE does occur. This way it will not show up as a "missing page".' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 02:36:56
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 13:37:30
User entered 'US3302327'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:10:20

US3302327

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:57:30
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:42

US3302327

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:57:30
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:10:22

US3302327

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:57:30
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:42

US3302327

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered 'SCRN'	System	21 Aug 2020 19:21:42



US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered (b) (6) 1986'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:10:23

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '33'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered 'YEARS'	System	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered '33'	System	21 Aug 2020 19:21:58

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered 'Female (F)'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '1'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50



US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:12:12

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:58:16
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:50

US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:00:03
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:58



US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered 'Aug 2020'	System	21 Aug 2020 19:21:58

US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered '2020'	System	21 Aug 2020 19:21:58

US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:00:03
User closed query 'Per CDM: Please clarify and review protocol version because protocol amendment 2 was effective until 20Aug2020. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:29:14
Query 'Per CDM: Please clarify and review protocol version because protocol amendment 2 was effective until 20Aug2020. Please review and update or clarify otherwise. Thank you!' answered with 'site didnt receive amendment until 24AUG2020' (Site from DM).	Brittany Belcher (b) (4)	29 Oct 2020 14:47:12
User opened query 'Per CDM: Please clarify and review protocol version because protocol amendment 2 was effective until 20Aug2020. Please review and update or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 08:14:08
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	23 Oct 2020 14:40:23
User entered 'Amendment 1 (1)'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:58

US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:00:03
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:58

US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:00:03
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:21:58

US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:00:03
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:21:58

US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:00:03
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:21:58

US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:00:03
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:10:22



US3302327

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:12:12

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered '1'	System	21 Aug 2020 19:22:03

US3302327

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:01
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:03

US3302327

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:12:12

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:02:15
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:08

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered '14:51'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered '21 Aug 2020 14:51'	System	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered '70' in	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46
DataPoint set to visible.	System	21 Aug 2020 19:22:03



US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered '145' lb	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46
DataPoint set to visible.	System	21 Aug 2020 19:22:03

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
Amendment Manager: User entered '20.84884'	System	17 Sep 2020 00:19:07
User entered '20.8'	System	21 Aug 2020 19:22:46
DataPoint set to visible.	System	21 Aug 2020 19:22:03

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered 'kg/m2'	System	21 Aug 2020 19:22:46
DataPoint set to visible.	System	21 Aug 2020 19:22:03

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:04:24
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:10:42
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 14:07:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:22
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:06:54
User entered '98.2' F	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered empty; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:22
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:22
User entered '86'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered 'bpm'	System	21 Aug 2020 19:22:46



US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:22
User entered '14'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered 'breaths/min'	System	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:22
User entered '116'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered 'mmHg'	System	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:04:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:22
User entered '77'	Brittany Belcher (b) (4)	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered 'mmHg'	System	21 Aug 2020 19:22:46

US3302327

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01



US3302327

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:05:04
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:05

US3302327

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:05:04
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:05

US3302327

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:49
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:15

US3302327

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User closed query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' (Site from DM).	(b) (4)	
Query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' answered with 'barrier method such as condoms and spermicide. Would these be entered in CM?' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 06:00:43
User opened query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' (Site from DM).	brittany cooksey (b) (4)	03 Feb 2021 14:18:13
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 11:57:24
	(b) (4), (b) (6)	03 Nov 2020 14:08:49
	Brittany Belcher (b) (4)	21 Aug 2020 19:23:15

US3302327

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:49
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:23:15

US3302327

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:12

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:08:49
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:23:15

US3302327

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:49
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:23:15

US3302327

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:12

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:49
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:15



US3302327

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:49
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:23:15

US3302327

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:12:12

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:08:49
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:15

US3302327

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:09:14
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:24:05

US3302327

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:09:14
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 19:24:05

US3302327

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:09:14
User entered 'Urine (URINE)'	Brittany Belcher (b) (4)	21 Aug 2020 19:24:05

US3302327

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:09:14
User entered 'Negative (NEGATIVE)'	Brittany Belcher (b) (4)	21 Aug 2020 19:24:05

US3302327

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:09:14
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:24:05

US3302327

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:09:14
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:24:05



US3302327

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:09:14
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:24:05

US3302327

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User entered empty.	System	21 Aug 2020 19:24:05

US3302327

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Form: Risk of Exposure

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[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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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)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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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)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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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)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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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)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38



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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)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Educators and Students](#) (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:14:20
User entered '0' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 18:50:33
User entered '1'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 02:36:32
DataPoint Un-verified.	Brittany Belcher (b) (4)	03 Nov 2020 18:50:33
User entered '1' reason for change: Data Entry Error	Brittany Belcher (b) (4)	03 Nov 2020 18:50:33
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4) (b) (4)	19 Feb 2021 19:14:20
User entered '0'	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:12:12

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:51:01
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:13:17
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:23:38

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:07
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:09



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:07
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:07
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'VISIT1'	System	21 Aug 2020 19:51:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:31
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:11:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:31
User entered '107219'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:11:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:31
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 19:11:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

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)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:31
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

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)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:31
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:17



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:31
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:31
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:31
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:12:12

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 02:36:08
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 15:50:45
DataPoint set to visible.	System	23 Oct 2020 14:40:23
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:10:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:20:10
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:20:07
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:18:54
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:10:37
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 14:07:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:06:46
User entered '70' in	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered '145' lb	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:20:10
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:20:07
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:18:54
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:10:37
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 14:07:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:06:46
User entered '70' in	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered '145' lb	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '21 Aug 2020' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '14:51' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '21 Aug 2020 14:51'	System	07 Oct 2020 14:07:01
User entered empty.	System	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '98.2' F reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24



US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '86' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'bpm'	System	07 Oct 2020 14:07:01
User entered empty.	System	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '14' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'breaths/min'	System	07 Oct 2020 14:07:01
User entered empty.	System	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '116' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	07 Oct 2020 14:07:01
User entered empty.	System	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '77' reason for change: Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	07 Oct 2020 14:07:01
User entered empty.	System	21 Aug 2020 20:19:24



US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:20:10
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 14:20:07
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:18:54
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 07:10:37
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'done' (Site from DM).	Brittany Belcher (b) (4)	07 Oct 2020 14:07:04
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:06:46
User entered '70' in	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:18:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Brittany Belcher (b) (4)	07 Oct 2020 14:07:01
User entered '145' lb	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '16:09'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '21 Aug 2020 16:09'	System	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '98.2' F	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '73'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'bpm'	System	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '18'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'breaths/min'	System	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '108'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	21 Aug 2020 20:19:24



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:19:43
User entered '68'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:24

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	21 Aug 2020 20:19:24

US3302327

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:20:48
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:29

US3302327

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:20:48
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:29

US3302327

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:02
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:33

US3302327

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:02
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:33

US3302327

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:02
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:33

US3302327

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:02
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:33



US3302327

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:02
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:33

US3302327

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:02
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:33

US3302327

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:02
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 20:19:33

US3302327

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered empty.	System	21 Aug 2020 20:19:33

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

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)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24
User entered empty.	Brittany Belcher (b) (4)	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 19:51:37



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24
User entered '15:39'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '21 Aug 2020 15:39'	System	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:24
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 14:21:24
User entered 'ONCE'	System	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 19:51:37

US3302327

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:40
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:44

US3302327

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:40
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:44



US3302327

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:21:40
User entered '15:04'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:44

US3302327

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '21 Aug 2020 15:04'	System	21 Aug 2020 20:19:44

US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:22:00
User entered '21 Aug 2020'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:58

US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:58

US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:22:00
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:58

US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:22:00
User entered '15:01'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:58

US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '21 Aug 2020 15:01'	System	21 Aug 2020 20:19:58

US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:58



US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:22:00
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 19:46:58
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:58

US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:22:00
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	20 Oct 2020 19:46:58
User entered '15:01'	Brittany Belcher (b) (4)	21 Aug 2020 20:19:58

US3302327

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered empty.	System	20 Oct 2020 19:46:58
User entered '21 Aug 2020 15:01'	System	21 Aug 2020 20:19:58

US3302327

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:22:22
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	21 Aug 2020 20:20:02

US3302327

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	21 Aug 2020 20:20:02

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T15:59:22', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6583c805-a7ad-4031-8400-dc7108ef7ad8' User entered 'Yes (Y)'	System	21 Aug 2020 19:59:41
	System	21 Aug 2020 19:59:41

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T15:59:29', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6583c805-a7ad-4031-8400-dc7108ef7ad8' User entered '98.2'	System	21 Aug 2020 19:59:41
	System	21 Aug 2020 19:59:41



US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T15:59:33', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6583c805-a7ad-4031-8400-dc7108ef7ad8'	System	21 Aug 2020 19:59:41
User entered 'No (N)'	System	21 Aug 2020 19:59:41

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T15:59:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6583c805-a7ad-4031-8400-dc7108ef7ad8' User entered '21 Aug 2020 15:59'	System	21 Aug 2020 19:59:41
	System	21 Aug 2020 19:59:41

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 15:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 18:29'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:40:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f70de526-8282-4c78-84e6-58e45c499b25' User entered 'Yes (Y)'	System	22 Aug 2020 12:41:30
	System	22 Aug 2020 12:41:30

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:41:05', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f70de526-8282-4c78-84e6-58e45c499b25' User entered '97.7'	System	22 Aug 2020 12:41:30
	System	22 Aug 2020 12:41:30

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:41:08', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f70de526-8282-4c78-84e6-58e45c499b25' User entered 'No (N)'	System	22 Aug 2020 12:41:30
	System	22 Aug 2020 12:41:30



US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:41:26', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f70de526-8282-4c78-84e6-58e45c499b25' User entered '22 Aug 2020 08:41'	System	22 Aug 2020 12:41:30
	System	22 Aug 2020 12:41:30

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 19:24'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 2'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:35:26', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'bafb179e-1b5f-4983-a17c-6411a285ed05' User entered 'Yes (Y)'	System	23 Aug 2020 13:35:42
	System	23 Aug 2020 13:35:42

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:35:32', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'bafb179e-1b5f-4983-a17c-6411a285ed05' User entered '97.7'	System	23 Aug 2020 13:35:42
	System	23 Aug 2020 13:35:42

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:35:36', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'bafb179e-1b5f-4983-a17c-6411a285ed05' User entered 'No (N)'	System	23 Aug 2020 13:35:42
	System	23 Aug 2020 13:35:42

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:35:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'bafb179e-1b5f-4983-a17c-6411a285ed05' User entered '23 Aug 2020 09:35'	System	23 Aug 2020 13:35:42
	System	23 Aug 2020 13:35:42



US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 3'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:42:44', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4eb6227a-659b-4635-891f-9d19c1bfe13a' User entered 'Yes (Y)'	System	24 Aug 2020 11:43:00
	System	24 Aug 2020 11:43:00

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:42:51', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4eb6227a-659b-4635-891f-9d19c1bfe13a' User entered '97.6'	System	24 Aug 2020 11:43:00
	System	24 Aug 2020 11:43:00

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:42:54', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4eb6227a-659b-4635-891f-9d19c1bfe13a' User entered 'No (N)'	System	24 Aug 2020 11:43:00
	System	24 Aug 2020 11:43:00

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:42:58', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4eb6227a-659b-4635-891f-9d19c1bfe13a' User entered '24 Aug 2020 07:42'	System	24 Aug 2020 11:43:00
	System	24 Aug 2020 11:43:00

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 4'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:49:36', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7b3be6b9-23cc-4c63-8839-6e868fd64b42'	System	25 Aug 2020 11:49:55
User entered 'Yes (Y)'	System	25 Aug 2020 11:49:55

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:49:43', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7b3be6b9-23cc-4c63-8839-6e868fd64b42'	System	25 Aug 2020 11:49:55
User entered '97.7'	System	25 Aug 2020 11:49:55

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:49:48', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7b3be6b9-23cc-4c63-8839-6e868fd64b42'	System	25 Aug 2020 11:49:55
User entered 'No (N)'	System	25 Aug 2020 11:49:55

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:49:53', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7b3be6b9-23cc-4c63-8839-6e868fd64b42'	System	25 Aug 2020 11:49:55
User entered '25 Aug 2020 07:49'	System	25 Aug 2020 11:49:55

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 5'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:15', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'eb5ec14e-12bb-4b32-a79b-5f2c814ea596' User entered 'Yes (Y)'	System	26 Aug 2020 11:32:29
	System	26 Aug 2020 11:32:29

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:21', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'eb5ec14e-12bb-4b32-a79b-5f2c814ea596' User entered '97.9'	System	26 Aug 2020 11:32:29
	System	26 Aug 2020 11:32:29

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:25', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'eb5ec14e-12bb-4b32-a79b-5f2c814ea596'	System	26 Aug 2020 11:32:29
User entered 'No (N)'	System	26 Aug 2020 11:32:29

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:28', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'eb5ec14e-12bb-4b32-a79b-5f2c814ea596' User entered '26 Aug 2020 07:32'	System	26 Aug 2020 11:32:29
	System	26 Aug 2020 11:32:29

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 6'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:14:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '66ecf71e-c278-466f-bc27-2adfb4b1d311'	System	27 Aug 2020 12:14:56
User entered 'Yes (Y)'	System	27 Aug 2020 12:14:56

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:14:42', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '66ecf71e-c278-466f-bc27-2adfb4b1d311' User entered '98.2'	System	27 Aug 2020 12:14:56
	System	27 Aug 2020 12:14:56

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:14:51', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '66ecf71e-c278-466f-bc27-2adfb4b1d311'	System	27 Aug 2020 12:14:56
User entered 'No (N)'	System	27 Aug 2020 12:14:56

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:14:54', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '66ecf71e-c278-466f-bc27-2adfb4b1d311'	System	27 Aug 2020 12:14:56
User entered '27 Aug 2020 08:14'	System	27 Aug 2020 12:14:56

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 7'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '29a71f5e-e5e8-417c-ae86-483320ccfd8c' User entered 'Yes (Y)'	System	28 Aug 2020 12:00:36
	System	28 Aug 2020 12:00:36



US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:24', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '29a71f5e-e5e8-417c-ae86-483320ccfd8c' User entered '98.0'	System	28 Aug 2020 12:00:36
	System	28 Aug 2020 12:00:36

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:29', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '29a71f5e-e5e8-417c-ae86-483320ccfd8c' User entered 'No (N)'	System	28 Aug 2020 12:00:36
	System	28 Aug 2020 12:00:36

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:32', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '29a71f5e-e5e8-417c-ae86-483320ccfd8c' User entered '28 Aug 2020 08:00'	System	28 Aug 2020 12:00:36
	System	28 Aug 2020 12:00:36

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T15:59:49', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'afa2644d-6440-4c80-b9b7-bcdea63904de' User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 20:01:24
	System	21 Aug 2020 20:01:24

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:00:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'afa2644d-6440-4c80-b9b7-bcdea63904de' User entered 'Yes (Y)'	System	21 Aug 2020 20:01:24
	System	21 Aug 2020 20:01:24



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:00:32', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'afa2644d-6440-4c80-b9b7-bcdea63904de' User entered '1'	System	21 Aug 2020 20:01:24
	System	21 Aug 2020 20:01:24

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:00:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'afa2644d-6440-4c80-b9b7-bcdea63904de' User entered 'Yes (Y)'	System	21 Aug 2020 20:01:24
	System	21 Aug 2020 20:01:24

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'afa2644d-6440-4c80-b9b7-bcdea63904de' User entered '1'	System	21 Aug 2020 20:01:24
	System	21 Aug 2020 20:01:24

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:11', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'afa2644d-6440-4c80-b9b7-bcdea63904de' User entered 'None (1)'	System	21 Aug 2020 20:01:24
	System	21 Aug 2020 20:01:24

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:21', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'afa2644d-6440-4c80-b9b7-bcdea63904de' User entered '21 Aug 2020 16:01'	System	21 Aug 2020 20:01:24
	System	21 Aug 2020 20:01:24

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 15:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 18:29'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:41:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cf52464-05d8-4dda-aa06-28539b15a558'	System	22 Aug 2020 12:42:57
User entered 'None (1)'	System	22 Aug 2020 12:42:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:42:06', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cf52464-05d8-4dda-aa06-28539b15a558'	System	22 Aug 2020 12:42:57
User entered 'No (N)'	System	22 Aug 2020 12:42:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:42:31', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cf52464-05d8-4dda-aa06-28539b15a558'	System	22 Aug 2020 12:42:57
User entered 'Yes (Y)'	System	22 Aug 2020 12:42:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:42:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cf52464-05d8-4dda-aa06-28539b15a558'	System	22 Aug 2020 12:42:57
User entered '1'	System	22 Aug 2020 12:42:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:42:46', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cf52464-05d8-4dda-aa06-28539b15a558'	System	22 Aug 2020 12:42:57
User entered 'None (1)'	System	22 Aug 2020 12:42:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:42:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cf52464-05d8-4dda-aa06-28539b15a558' User entered '22 Aug 2020 08:42'	System	22 Aug 2020 12:42:57
	System	22 Aug 2020 12:42:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 19:24'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 2'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:35:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '008cd3a3-c60c-4f64-a37d-3bb3ba48a2c2'	System	23 Aug 2020 13:36:11
User entered 'None (1)'	System	23 Aug 2020 13:36:11

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:35:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '008cd3a3-c60c-4f64-a37d-3bb3ba48a2c2' User entered 'No (N)'	System	23 Aug 2020 13:36:11
	System	23 Aug 2020 13:36:11

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:02', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '008cd3a3-c60c-4f64-a37d-3bb3ba48a2c2'	System	23 Aug 2020 13:36:11
User entered 'No (N)'	System	23 Aug 2020 13:36:11

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:06', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '008cd3a3-c60c-4f64-a37d-3bb3ba48a2c2'	System	23 Aug 2020 13:36:11
User entered 'None (1)'	System	23 Aug 2020 13:36:11

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:09', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '008cd3a3-c60c-4f64-a37d-3bb3ba48a2c2' User entered '23 Aug 2020 09:36'	System	23 Aug 2020 13:36:11
	System	23 Aug 2020 13:36:11

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 3'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:05', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8dbd6bc1-d04c-4b61-b195-867b633f7919'	System	24 Aug 2020 11:43:21
User entered 'None (1)'	System	24 Aug 2020 11:43:21

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:08', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8dbd6bc1-d04c-4b61-b195-867b633f7919'	System	24 Aug 2020 11:43:21
User entered 'No (N)'	System	24 Aug 2020 11:43:21

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:11', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8dbd6bc1-d04c-4b61-b195-867b633f7919' User entered 'No (N)'	System	24 Aug 2020 11:43:21
	System	24 Aug 2020 11:43:21

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:16', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8dbd6bc1-d04c-4b61-b195-867b633f7919'	System	24 Aug 2020 11:43:21
User entered 'None (1)'	System	24 Aug 2020 11:43:21

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8dbd6bc1-d04c-4b61-b195-867b633f7919' User entered '24 Aug 2020 07:43'	System	24 Aug 2020 11:43:21
	System	24 Aug 2020 11:43:21

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 4'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:49:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd6e18ed1-f9f3-4c1d-96a0-72eaa311f3d6'	System	25 Aug 2020 11:50:18
User entered 'None (1)'	System	25 Aug 2020 11:50:18

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:02', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd6e18ed1-f9f3-4c1d-96a0-72eaa311f3d6'	System	25 Aug 2020 11:50:18
User entered 'No (N)'	System	25 Aug 2020 11:50:18

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:07', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd6e18ed1-f9f3-4c1d-96a0-72eaa311f3d6'	System	25 Aug 2020 11:50:18
User entered 'No (N)'	System	25 Aug 2020 11:50:18

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:12', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd6e18ed1-f9f3-4c1d-96a0-72eaa311f3d6'	System	25 Aug 2020 11:50:18
User entered 'None (1)'	System	25 Aug 2020 11:50:18

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:15', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd6e18ed1-f9f3-4c1d-96a0-72eaa311f3d6' User entered '25 Aug 2020 07:50'	System	25 Aug 2020 11:50:18
	System	25 Aug 2020 11:50:18

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 5'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd5c5c630-0da4-4057-b573-19ee31e94cff'	System	26 Aug 2020 11:32:50
User entered 'None (1)'	System	26 Aug 2020 11:32:50

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd5c5c630-0da4-4057-b573-19ee31e94cff'	System	26 Aug 2020 11:32:50
User entered 'No (N)'	System	26 Aug 2020 11:32:50

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:41', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd5c5c630-0da4-4057-b573-19ee31e94cff'	System	26 Aug 2020 11:32:50
User entered 'No (N)'	System	26 Aug 2020 11:32:50

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:44', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd5c5c630-0da4-4057-b573-19ee31e94cff'	System	26 Aug 2020 11:32:50
User entered 'None (1)'	System	26 Aug 2020 11:32:50

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:47', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd5c5c630-0da4-4057-b573-19ee31e94cff' User entered '26 Aug 2020 07:32'	System	26 Aug 2020 11:32:50
	System	26 Aug 2020 11:32:50

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 6'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:14:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'af11ed12-c171-44bb-8713-587f66bcae37'	System	27 Aug 2020 12:15:13
User entered 'None (1)'	System	27 Aug 2020 12:15:13

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:02', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'af11ed12-c171-44bb-8713-587f66bcae37' User entered 'No (N)'	System	27 Aug 2020 12:15:13
	System	27 Aug 2020 12:15:13

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:05', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'af11ed12-c171-44bb-8713-587f66bcae37' User entered 'No (N)'	System	27 Aug 2020 12:15:13
	System	27 Aug 2020 12:15:13

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:08', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'af11ed12-c171-44bb-8713-587f66bcae37'	System	27 Aug 2020 12:15:13
User entered 'None (1)'	System	27 Aug 2020 12:15:13

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:10', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'af11ed12-c171-44bb-8713-587f66bcae37' User entered '27 Aug 2020 08:15'	System	27 Aug 2020 12:15:13
	System	27 Aug 2020 12:15:13

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 7'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '28dceb5f-b0a7-40ff-91b3-c23f9af86ff6'	System	28 Aug 2020 12:00:57
User entered 'None (1)'	System	28 Aug 2020 12:00:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:42', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '28dceb5f-b0a7-40ff-91b3-c23f9af86ff6'	System	28 Aug 2020 12:00:57
User entered 'No (N)'	System	28 Aug 2020 12:00:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:45', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '28dceb5f-b0a7-40ff-91b3-c23f9af86ff6'	System	28 Aug 2020 12:00:57
User entered 'No (N)'	System	28 Aug 2020 12:00:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:52', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '28dceb5f-b0a7-40ff-91b3-c23f9af86ff6'	System	28 Aug 2020 12:00:57
User entered 'None (1)'	System	28 Aug 2020 12:00:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:00:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '28dceb5f-b0a7-40ff-91b3-c23f9af86ff6' User entered '28 Aug 2020 08:00'	System	28 Aug 2020 12:00:57
	System	28 Aug 2020 12:00:57

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:25', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a0b57383-2e76-4b85-89b6-9049a8a71469' User entered 'None (0)'	System	21 Aug 2020 20:01:56
	System	21 Aug 2020 20:01:56

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:29', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a0b57383-2e76-4b85-89b6-9049a8a71469' User entered 'None (0)'	System	21 Aug 2020 20:01:56
	System	21 Aug 2020 20:01:56

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:34', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a0b57383-2e76-4b85-89b6-9049a8a71469' User entered 'None (0)'	System	21 Aug 2020 20:01:56
	System	21 Aug 2020 20:01:56

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a0b57383-2e76-4b85-89b6-9049a8a71469' User entered 'None (0)'	System	21 Aug 2020 20:01:56
	System	21 Aug 2020 20:01:56

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a0b57383-2e76-4b85-89b6-9049a8a71469'	System	21 Aug 2020 20:01:56
User entered 'None (0)'	System	21 Aug 2020 20:01:56

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:43', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a0b57383-2e76-4b85-89b6-9049a8a71469' User entered 'None (0)'	System	21 Aug 2020 20:01:56
	System	21 Aug 2020 20:01:56

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:47', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a0b57383-2e76-4b85-89b6-9049a8a71469'	System	21 Aug 2020 20:01:56
User entered 'No (N)'	System	21 Aug 2020 20:01:56



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-21T16:01:51', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a0b57383-2e76-4b85-89b6-9049a8a71469' User entered '21 Aug 2020 16:01'	System	21 Aug 2020 20:01:56
	System	21 Aug 2020 20:01:56

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 15:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 18:29'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:43:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7f4c735f-cd9b-4dfc-bf37-1b774af8dcd'	System	22 Aug 2020 12:43:41
User entered 'None (0)'	System	22 Aug 2020 12:43:41

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:43:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7f4c735f-cd9b-4dfc-bf37-1b774af8dcd'	System	22 Aug 2020 12:43:41
User entered 'None (0)'	System	22 Aug 2020 12:43:41

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:43:25', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7f4c735f-cd9b-4dfc-bf37-1b774af8dcd'	System	22 Aug 2020 12:43:41
User entered 'None (0)'	System	22 Aug 2020 12:43:41

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:43:27', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7f4c735f-cd9b-4dfc-bf37-1b774af8dcd'	System	22 Aug 2020 12:43:41
User entered 'None (0)'	System	22 Aug 2020 12:43:41



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:43:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7f4c735f-cd9b-4dfc-bf37-1b774af8dcd'	System	22 Aug 2020 12:43:41
User entered 'None (0)'	System	22 Aug 2020 12:43:41

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:43:32', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7f4c735f-cd9b-4dfc-bf37-1b774af8dcd'	System	22 Aug 2020 12:43:41
User entered 'None (0)'	System	22 Aug 2020 12:43:41

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:43:36', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7f4c735f-cd9b-4dfc-bf37-1b774af8dcd'	System	22 Aug 2020 12:43:41
User entered 'No (N)'	System	22 Aug 2020 12:43:41

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-22T08:43:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7f4c735f-cd9b-4dfc-bf37-1b774af8dcd'	System	22 Aug 2020 12:43:41
User entered '22 Aug 2020 08:43'	System	22 Aug 2020 12:43:41

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Aug 2020 19:24'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 2'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8ce200aa-d95a-45bf-b2c3-60fc3b5ab664' User entered 'None (0)'	System	23 Aug 2020 13:36:40
	System	23 Aug 2020 13:36:40



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:21', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8ce200aa-d95a-45bf-b2c3-60fc3b5ab664' User entered 'None (0)'	System	23 Aug 2020 13:36:40
	System	23 Aug 2020 13:36:40

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:23', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8ce200aa-d95a-45bf-b2c3-60fc3b5ab664' User entered 'None (0)'	System	23 Aug 2020 13:36:40
	System	23 Aug 2020 13:36:40

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:26', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8ce200aa-d95a-45bf-b2c3-60fc3b5ab664' User entered 'None (0)'	System	23 Aug 2020 13:36:40
	System	23 Aug 2020 13:36:40

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:28', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8ce200aa-d95a-45bf-b2c3-60fc3b5ab664' User entered 'None (0)'	System	23 Aug 2020 13:36:40
	System	23 Aug 2020 13:36:40

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8ce200aa-d95a-45bf-b2c3-60fc3b5ab664'	System	23 Aug 2020 13:36:40
User entered 'None (0)'	System	23 Aug 2020 13:36:40

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8ce200aa-d95a-45bf-b2c3-60fc3b5ab664' User entered 'No (N)'	System	23 Aug 2020 13:36:40
	System	23 Aug 2020 13:36:40

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-23T09:36:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '8ce200aa-d95a-45bf-b2c3-60fc3b5ab664' User entered '23 Aug 2020 09:36'	System	23 Aug 2020 13:36:40
	System	23 Aug 2020 13:36:40

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 3'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:25', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5eff01b-65d6-4bb4-ae2a-838d42005396'	System	24 Aug 2020 11:43:47
User entered 'None (0)'	System	24 Aug 2020 11:43:47

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:28', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5eff01b-65d6-4bb4-ae2a-838d42005396'	System	24 Aug 2020 11:43:47
User entered 'None (0)'	System	24 Aug 2020 11:43:47

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5eff01b-65d6-4bb4-ae2a-838d42005396'	System	24 Aug 2020 11:43:47
User entered 'None (0)'	System	24 Aug 2020 11:43:47

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:32', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5eff01b-65d6-4bb4-ae2a-838d42005396'	System	24 Aug 2020 11:43:47
User entered 'None (0)'	System	24 Aug 2020 11:43:47

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5eff01b-65d6-4bb4-ae2a-838d42005396' User entered 'None (0)'	System	24 Aug 2020 11:43:47
	System	24 Aug 2020 11:43:47

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:37', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5eff01b-65d6-4bb4-ae2a-838d42005396' User entered 'None (0)'	System	24 Aug 2020 11:43:47
	System	24 Aug 2020 11:43:47



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:42', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5eff01b-65d6-4bb4-ae2a-838d42005396' User entered 'No (N)'	System	24 Aug 2020 11:43:47
	System	24 Aug 2020 11:43:47

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-24T07:43:44', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5eff01b-65d6-4bb4-ae2a-838d42005396'	System	24 Aug 2020 11:43:47
User entered '24 Aug 2020 07:43'	System	24 Aug 2020 11:43:47

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 4'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:22', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a5c92b8-686f-4e83-89ab-daa0d92d1efd' User entered 'None (0)'	System	25 Aug 2020 11:50:50
	System	25 Aug 2020 11:50:50

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:26', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a5c92b8-686f-4e83-89ab-daa0d92d1efd' User entered 'None (0)'	System	25 Aug 2020 11:50:50
	System	25 Aug 2020 11:50:50

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a5c92b8-686f-4e83-89ab-daa0d92d1efd' User entered 'None (0)'	System	25 Aug 2020 11:50:50
	System	25 Aug 2020 11:50:50



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:34', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a5c92b8-686f-4e83-89ab-daa0d92d1efd' User entered 'None (0)'	System	25 Aug 2020 11:50:50
	System	25 Aug 2020 11:50:50

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:37', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a5c92b8-686f-4e83-89ab-daa0d92d1efd' User entered 'None (0)'	System	25 Aug 2020 11:50:50
	System	25 Aug 2020 11:50:50

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a5c92b8-686f-4e83-89ab-daa0d92d1efd' User entered 'None (0)'	System	25 Aug 2020 11:50:50
	System	25 Aug 2020 11:50:50

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:46', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a5c92b8-686f-4e83-89ab-daa0d92d1efd' User entered 'No (N)'	System	25 Aug 2020 11:50:50
	System	25 Aug 2020 11:50:50

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-25T07:50:48', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a5c92b8-686f-4e83-89ab-daa0d92d1efd' User entered '25 Aug 2020 07:50'	System	25 Aug 2020 11:50:50
	System	25 Aug 2020 11:50:50

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 5'	System	21 Aug 2020 19:51:37



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:52', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f2ed2bc5-22df-44c5-878c-53b1ba10f904' User entered 'None (0)'	System	26 Aug 2020 11:33:17
	System	26 Aug 2020 11:33:17

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:32:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f2ed2bc5-22df-44c5-878c-53b1ba10f904' User entered 'None (0)'	System	26 Aug 2020 11:33:17
	System	26 Aug 2020 11:33:17

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:33:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f2ed2bc5-22df-44c5-878c-53b1ba10f904'	System	26 Aug 2020 11:33:17
User entered 'None (0)'	System	26 Aug 2020 11:33:17

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:33:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f2ed2bc5-22df-44c5-878c-53b1ba10f904' User entered 'None (0)'	System	26 Aug 2020 11:33:17
	System	26 Aug 2020 11:33:17

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:33:06', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f2ed2bc5-22df-44c5-878c-53b1ba10f904'	System	26 Aug 2020 11:33:17
User entered 'None (0)'	System	26 Aug 2020 11:33:17

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:33:09', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f2ed2bc5-22df-44c5-878c-53b1ba10f904' User entered 'None (0)'	System	26 Aug 2020 11:33:17
	System	26 Aug 2020 11:33:17

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:33:12', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f2ed2bc5-22df-44c5-878c-53b1ba10f904'	System	26 Aug 2020 11:33:17
User entered 'No (N)'	System	26 Aug 2020 11:33:17

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-26T07:33:14', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f2ed2bc5-22df-44c5-878c-53b1ba10f904' User entered '26 Aug 2020 07:33'	System	26 Aug 2020 11:33:17
	System	26 Aug 2020 11:33:17



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 6'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:33', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'da530200-c8db-4fd4-9f2b-779da7cfaa8c'	System	27 Aug 2020 12:15:57
User entered 'No interference with activity (1)'	System	27 Aug 2020 12:15:57

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:36', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'da530200-c8db-4fd4-9f2b-779da7cfaa8c' User entered 'None (0)'	System	27 Aug 2020 12:15:57
	System	27 Aug 2020 12:15:57

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'da530200-c8db-4fd4-9f2b-779da7cfaa8c' User entered 'None (0)'	System	27 Aug 2020 12:15:57
	System	27 Aug 2020 12:15:57

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:41', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'da530200-c8db-4fd4-9f2b-779da7cfaa8c' User entered 'None (0)'	System	27 Aug 2020 12:15:57
	System	27 Aug 2020 12:15:57

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:44', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'da530200-c8db-4fd4-9f2b-779da7cfaa8c' User entered 'None (0)'	System	27 Aug 2020 12:15:57
	System	27 Aug 2020 12:15:57



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:47', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'da530200-c8db-4fd4-9f2b-779da7cfaa8c' User entered 'None (0)'	System	27 Aug 2020 12:15:57
	System	27 Aug 2020 12:15:57

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:49', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'da530200-c8db-4fd4-9f2b-779da7cfaa8c' User entered 'No (N)'	System	27 Aug 2020 12:15:57
	System	27 Aug 2020 12:15:57

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-27T08:15:54', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'da530200-c8db-4fd4-9f2b-779da7cfaa8c' User entered '27 Aug 2020 08:15'	System	27 Aug 2020 12:15:57
	System	27 Aug 2020 12:15:57

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 7'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:01:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6d1879be-32f4-4f27-9cf1-885fc7e9094d' User entered 'None (0)'	System	28 Aug 2020 12:01:23
	System	28 Aug 2020 12:01:23

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:01:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6d1879be-32f4-4f27-9cf1-885fc7e9094d' User entered 'None (0)'	System	28 Aug 2020 12:01:23
	System	28 Aug 2020 12:01:23



US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:01:06', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6d1879be-32f4-4f27-9cf1-885fc7e9094d' User entered 'None (0)'	System	28 Aug 2020 12:01:23
	System	28 Aug 2020 12:01:23

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:01:08', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6d1879be-32f4-4f27-9cf1-885fc7e9094d' User entered 'None (0)'	System	28 Aug 2020 12:01:23
	System	28 Aug 2020 12:01:23

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:01:11', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6d1879be-32f4-4f27-9cf1-885fc7e9094d' User entered 'None (0)'	System	28 Aug 2020 12:01:23
	System	28 Aug 2020 12:01:23

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:01:13', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6d1879be-32f4-4f27-9cf1-885fc7e9094d' User entered 'None (0)'	System	28 Aug 2020 12:01:23
	System	28 Aug 2020 12:01:23

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:01:16', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6d1879be-32f4-4f27-9cf1-885fc7e9094d' User entered 'No (N)'	System	28 Aug 2020 12:01:23
	System	28 Aug 2020 12:01:23

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-08-28T08:01:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '6d1879be-32f4-4f27-9cf1-885fc7e9094d' User entered '28 Aug 2020 08:01'	System	28 Aug 2020 12:01:23
	System	28 Aug 2020 12:01:23

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 19:51:37

US3302327

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 19:51:37



US3302327

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:23:18
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	28 Aug 2020 21:58:05

US3302327

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:23:18
User entered '28 Aug 2020'	Wendy Taylor (b) (4)	28 Aug 2020 21:58:05

US3302327

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:23:18
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	28 Aug 2020 21:58:05

US3302327

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:23:18
User entered empty.	Wendy Taylor (b) (4)	28 Aug 2020 21:58:05

US3302327

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:23:23
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	28 Aug 2020 21:58:11

US3302327

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	28 Aug 2020 21:58:11

US3302327

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:24:01
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	07 Sep 2020 17:30:37

US3302327

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:24:01
User entered '7 Sep 2020'	Wendy Taylor (b) (4)	07 Sep 2020 17:30:37



US3302327

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:24:01
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	07 Sep 2020 17:30:37

US3302327

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:24:01
User entered empty.	Wendy Taylor (b) (4)	07 Sep 2020 17:30:37

US3302327

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:24:08
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	07 Sep 2020 17:30:42

US3302327

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	07 Sep 2020 17:30:42

US3302327

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:54:31
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	11 Sep 2020 18:02:08

US3302327

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:54:31
User entered '11 Sep 2020'	Wendy Taylor (b) (4)	11 Sep 2020 18:02:08

US3302327

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:54:31
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	11 Sep 2020 18:02:08

US3302327

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:54:31
User entered empty.	Wendy Taylor (b) (4)	11 Sep 2020 18:02:08



US3302327

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:54:40
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	11 Sep 2020 18:02:01

US3302327

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	11 Sep 2020 18:02:01

US3302327

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:56:58
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 17:57:42

US3302327

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:56:58
User entered '18 Sep 2020'	Brittany Belcher (b) (4)	18 Sep 2020 17:57:42

US3302327

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:56:58
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	18 Sep 2020 17:57:42

US3302327

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'VISIT2'	System	18 Sep 2020 17:57:42

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User accepted default value 'Pre-Dose (PREDOSE)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27



US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '18 Sep 2020'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '13:35'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '18 Sep 2020 13:35'	System	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '98.7' F	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered empty.	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '79'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'bpm'	System	18 Sep 2020 18:43:27



US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '18'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'breaths/min'	System	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '103'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '74'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User accepted default value 'Post-Dose (POSTDOSE)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27



US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '18 Sep 2020'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '14:25'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '18 Sep 2020 14:25'	System	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '98.7' F	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered empty.	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '76'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'bpm'	System	18 Sep 2020 18:43:27



US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '16'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'breaths/min'	System	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '101'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:58:27
User entered '73'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	18 Sep 2020 18:43:27

US3302327

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:24:39
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:33

US3302327

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:24:39
User entered '18 Sep 2020'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:33



US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:00:47
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:44

US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:00:47
User entered '18 Sep 2020'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:44

US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:00:47
User entered 'Urine (URINE)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:44

US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:00:47
User entered 'Negative (NEGATIVE)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:44

US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:00:47
User entered 'No (N)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:44

US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:00:47
User entered empty.	Brittany Belcher (b) (4)	18 Sep 2020 18:43:44

US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:00:47
User entered empty.	Brittany Belcher (b) (4)	18 Sep 2020 18:43:44

US3302327

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered empty.	System	18 Sep 2020 18:43:44



US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:09
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:09
User entered empty.	Brittany Belcher (b) (4)	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

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)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:09
User entered empty.	Brittany Belcher (b) (4)	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:09
User entered '18 Sep 2020'	Brittany Belcher (b) (4)	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:09
User entered '13:55'	Brittany Belcher (b) (4)	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '18 Sep 2020 13:55'	System	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:01:09
User entered 'Left Arm (LEFT ARM)'	Brittany Belcher (b) (4)	18 Sep 2020 17:57:32



US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 15:01:09
User entered 'ONCE'	System	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 17:57:32

US3302327

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:06:04
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:53

US3302327

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:06:04
User entered '18 Sep 2020'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:53

US3302327

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:06:04
User entered '13:43'	Brittany Belcher (b) (4)	18 Sep 2020 18:43:53

US3302327

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '18 Sep 2020 13:43'	System	18 Sep 2020 18:43:53

US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:06:15
User entered '18 Sep 2020'	Brittany Belcher (b) (4)	18 Sep 2020 18:44:05

US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brittany Belcher (b) (4)	18 Sep 2020 18:44:05



US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:06:19
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 18:44:05

US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:06:21
User entered '13:41'	Brittany Belcher (b) (4)	18 Sep 2020 18:44:05

US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '18 Sep 2020 13:41'	System	18 Sep 2020 18:44:05

US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:12

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brittany Belcher (b) (4)	18 Sep 2020 18:44:05

US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:40:02
User closed query 'Please delete the duplicated details on Line 2. Kindly select "NO" for the question "Was the sampled collected?"' (Site from CRA).	(b) (4), (b) (6)	23 Dec 2020 17:39:57
Query 'Please delete the duplicated details on Line 2. Kindly select "NO" for the question "Was the sample collected?"' answered with 'updated' (Site from CRA)	Wendy Taylor (b) (4)	23 Dec 2020 03:31:21
User entered 'No (N)' reason for change: Data Entry Error	Wendy Taylor (b) (4)	23 Dec 2020 03:31:14
User opened query 'Please delete the duplicated details on Line 2. Kindly select "NO" for the question "Was the sampled collected?"' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 15:07:20
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 18:44:05

US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:40:02
User entered empty; reason for change Data Entry Error	Wendy Taylor (b) (4)	23 Dec 2020 03:31:14
User entered '13:41'	Brittany Belcher (b) (4)	18 Sep 2020 18:44:05

US3302327

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered empty.	System	23 Dec 2020 03:31:14
User entered '18 Sep 2020 13:41'	System	18 Sep 2020 18:44:05

US3302327

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:07:26
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	18 Sep 2020 18:44:08



US3302327

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	18 Sep 2020 18:44:08

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:15:17', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'fe109123-94f4-47ae-8dfe-93fb953315a1'	System	18 Sep 2020 18:15:58
User entered 'Yes (Y)'	System	18 Sep 2020 18:15:58

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:15:23', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'fe109123-94f4-47ae-8dfe-93fb953315a1' User entered '98.7'	System	18 Sep 2020 18:15:58
	System	18 Sep 2020 18:15:58

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:15:27', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'fe109123-94f4-47ae-8dfe-93fb953315a1'	System	18 Sep 2020 18:15:58
User entered 'No (N)'	System	18 Sep 2020 18:15:58

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:15:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'fe109123-94f4-47ae-8dfe-93fb953315a1'	System	18 Sep 2020 18:15:58
User entered '18 Sep 2020 14:15'	System	18 Sep 2020 18:15:58

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 14:15'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 16:45'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:25:50', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '213c9602-f7fc-47d6-9b1f-54e1f6ed33b2'	System	19 Sep 2020 11:26:13
User entered 'Yes (Y)'	System	19 Sep 2020 11:26:13

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '213c9602-f7fc-47d6-9b1f-54e1f6ed33b2'	System	19 Sep 2020 11:26:13
User entered '97.8'	System	19 Sep 2020 11:26:13

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:07', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '213c9602-f7fc-47d6-9b1f-54e1f6ed33b2'	System	19 Sep 2020 11:26:13
User entered 'No (N)'	System	19 Sep 2020 11:26:13

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:10', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '213c9602-f7fc-47d6-9b1f-54e1f6ed33b2' User entered '19 Sep 2020 07:26'	System	19 Sep 2020 11:26:13
	System	19 Sep 2020 11:26:13

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 17:40'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 2'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:03:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b2d06406-b1db-4158-9f6f-cb6a13c4a5b6'	System	20 Sep 2020 04:03:55
User entered 'Yes (Y)'	System	20 Sep 2020 04:03:55

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:03:47', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b2d06406-b1db-4158-9f6f-cb6a13c4a5b6'	System	20 Sep 2020 04:03:55
User entered '96.8'	System	20 Sep 2020 04:03:55

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:03:51', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b2d06406-b1db-4158-9f6f-cb6a13c4a5b6'	System	20 Sep 2020 04:03:55
User entered 'No (N)'	System	20 Sep 2020 04:03:55

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:03:54', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b2d06406-b1db-4158-9f6f-cb6a13c4a5b6' User entered '20 Sep 2020 00:03'	System	20 Sep 2020 04:03:55
	System	20 Sep 2020 04:03:55

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 3'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:24', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b089bca9-f7bd-41e6-888f-5f5a3645e101' User entered 'Yes (Y)'	System	20 Sep 2020 22:13:40
	System	20 Sep 2020 22:13:40



US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b089bca9-f7bd-41e6-888f-5f5a3645e101' User entered '97.7'	System	20 Sep 2020 22:13:40
	System	20 Sep 2020 22:13:40

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:33', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b089bca9-f7bd-41e6-888f-5f5a3645e101'	System	20 Sep 2020 22:13:40
User entered 'No (N)'	System	20 Sep 2020 22:13:40

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b089bca9-f7bd-41e6-888f-5f5a3645e101'	System	20 Sep 2020 22:13:40
User entered '20 Sep 2020 18:13'	System	20 Sep 2020 22:13:40

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 4'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:22', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7df17b44-95ba-4411-ba39-92cfa5e10f37'	System	22 Sep 2020 02:42:37
User entered 'Yes (Y)'	System	22 Sep 2020 02:42:37

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:28', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7df17b44-95ba-4411-ba39-92cfa5e10f37'	System	22 Sep 2020 02:42:37
User entered '97.4'	System	22 Sep 2020 02:42:37



US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:31', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7df17b44-95ba-4411-ba39-92cfa5e10f37'	System	22 Sep 2020 02:42:37
User entered 'No (N)'	System	22 Sep 2020 02:42:37

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:34', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7df17b44-95ba-4411-ba39-92cfa5e10f37'	System	22 Sep 2020 02:42:37
User entered '21 Sep 2020 22:42'	System	22 Sep 2020 02:42:37

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 5'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:26', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0918b0b0-7389-48cf-98ef-7f05e7761339'	System	23 Sep 2020 11:42:41
User entered 'Yes (Y)'	System	23 Sep 2020 11:42:41

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:32', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0918b0b0-7389-48cf-98ef-7f05e7761339' User entered '97.6'	System	23 Sep 2020 11:42:41
	System	23 Sep 2020 11:42:41

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0918b0b0-7389-48cf-98ef-7f05e7761339'	System	23 Sep 2020 11:42:41
User entered 'No (N)'	System	23 Sep 2020 11:42:41



US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0918b0b0-7389-48cf-98ef-7f05e7761339' User entered '23 Sep 2020 07:42'	System	23 Sep 2020 11:42:41
	System	23 Sep 2020 11:42:41

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 6'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:12', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5d14416-0292-491b-ac31-bf61a4a0d08a' User entered 'Yes (Y)'	System	24 Sep 2020 02:06:25
	System	24 Sep 2020 02:06:25

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:16', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5d14416-0292-491b-ac31-bf61a4a0d08a' User entered '96.7'	System	24 Sep 2020 02:06:25
	System	24 Sep 2020 02:06:25

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:20', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5d14416-0292-491b-ac31-bf61a4a0d08a'	System	24 Sep 2020 02:06:25
User entered 'No (N)'	System	24 Sep 2020 02:06:25

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:22', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b5d14416-0292-491b-ac31-bf61a4a0d08a' User entered '23 Sep 2020 22:06'	System	24 Sep 2020 02:06:25
	System	24 Sep 2020 02:06:25



US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 7'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:00:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0fcb01f-df16-4ebb-899e-ab4371e74439' User entered 'Yes (Y)'	System	25 Sep 2020 12:00:53
	System	25 Sep 2020 12:00:53

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:00:45', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0fcb01f-df16-4ebb-899e-ab4371e74439' User entered '97.6'	System	25 Sep 2020 12:00:53
	System	25 Sep 2020 12:00:53

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:00:48', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0fcba01f-df16-4ebb-899e-ab4371e74439'	System	25 Sep 2020 12:00:53
User entered 'No (N)'	System	25 Sep 2020 12:00:53

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:00:50', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0fcba01f-df16-4ebb-899e-ab4371e74439' User entered '25 Sep 2020 08:00'	System	25 Sep 2020 12:00:53
	System	25 Sep 2020 12:00:53

US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:15:47', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a85a6313-572c-4dfb-96b8-be7fd8ef6d45'	System	18 Sep 2020 18:16:09
User entered 'None (1)'	System	18 Sep 2020 18:16:09

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:15:52', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a85a6313-572c-4dfb-96b8-be7fd8ef6d45'	System	18 Sep 2020 18:16:09
User entered 'No (N)'	System	18 Sep 2020 18:16:09

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:15:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a85a6313-572c-4dfb-96b8-be7fd8ef6d45'	System	18 Sep 2020 18:16:09
User entered 'No (N)'	System	18 Sep 2020 18:16:09

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:15:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a85a6313-572c-4dfb-96b8-be7fd8ef6d45'	System	18 Sep 2020 18:16:09
User entered 'None (1)'	System	18 Sep 2020 18:16:09

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a85a6313-572c-4dfb-96b8-be7fd8ef6d45' User entered '18 Sep 2020 14:16'	System	18 Sep 2020 18:16:09
	System	18 Sep 2020 18:16:09

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 14:15'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 16:45'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b22c4d5e-d9d2-4a37-979a-b024a2c4ba67'	System	19 Sep 2020 11:26:33
User entered 'None (1)'	System	19 Sep 2020 11:26:33

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:22', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b22c4d5e-d9d2-4a37-979a-b024a2c4ba67' User entered 'No (N)'	System	19 Sep 2020 11:26:33
	System	19 Sep 2020 11:26:33

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:25', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b22c4d5e-d9d2-4a37-979a-b024a2c4ba67' User entered 'No (N)'	System	19 Sep 2020 11:26:33
	System	19 Sep 2020 11:26:33

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:28', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b22c4d5e-d9d2-4a37-979a-b024a2c4ba67'	System	19 Sep 2020 11:26:33
User entered 'None (1)'	System	19 Sep 2020 11:26:33

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:31', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b22c4d5e-d9d2-4a37-979a-b024a2c4ba67' User entered '19 Sep 2020 07:26'	System	19 Sep 2020 11:26:33
	System	19 Sep 2020 11:26:33

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 17:40'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 2'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:07', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '693aa391-8900-4387-9f11-7179bdd48748'	System	20 Sep 2020 04:04:26
User entered 'None (1)'	System	20 Sep 2020 04:04:26

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:11', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '693aa391-8900-4387-9f11-7179bdd48748' User entered 'No (N)'	System	20 Sep 2020 04:04:26
	System	20 Sep 2020 04:04:26

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:13', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '693aa391-8900-4387-9f11-7179bdd48748' User entered 'No (N)'	System	20 Sep 2020 04:04:26
	System	20 Sep 2020 04:04:26

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:18', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '693aa391-8900-4387-9f11-7179bdd48748'	System	20 Sep 2020 04:04:26
User entered 'None (1)'	System	20 Sep 2020 04:04:26

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:24', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '693aa391-8900-4387-9f11-7179bdd48748' User entered '20 Sep 2020 00:04'	System	20 Sep 2020 04:04:26
	System	20 Sep 2020 04:04:26

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 3'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7d28fb7f-9361-4de4-abde-a7d888cb5669'	System	20 Sep 2020 22:13:51
User entered 'None (1)'	System	20 Sep 2020 22:13:51

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:43', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7d28fb7f-9361-4de4-abde-a7d888cb5669' User entered 'No (N)'	System	20 Sep 2020 22:13:51
	System	20 Sep 2020 22:13:51

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:45', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7d28fb7f-9361-4de4-abde-a7d888cb5669' User entered 'No (N)'	System	20 Sep 2020 22:13:51
	System	20 Sep 2020 22:13:51

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:47', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7d28fb7f-9361-4de4-abde-a7d888cb5669'	System	20 Sep 2020 22:13:51
User entered 'None (1)'	System	20 Sep 2020 22:13:51

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:50', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '7d28fb7f-9361-4de4-abde-a7d888cb5669' User entered '20 Sep 2020 18:13'	System	20 Sep 2020 22:13:51
	System	20 Sep 2020 22:13:51

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 4'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'e1f1b91a-7528-4b77-bfcc-ae0bedb2d2ad'	System	22 Sep 2020 02:42:50
User entered 'None (1)'	System	22 Sep 2020 02:42:50

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:41', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'e1f1b91a-7528-4b77-bfcc-ae0bedb2d2ad'	System	22 Sep 2020 02:42:50
User entered 'No (N)'	System	22 Sep 2020 02:42:50

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:43', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'e1f1b91a-7528-4b77-bfcc-ae0bedb2d2ad'	System	22 Sep 2020 02:42:50
User entered 'No (N)'	System	22 Sep 2020 02:42:50

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:46', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'e1f1b91a-7528-4b77-bfcc-ae0bedb2d2ad'	System	22 Sep 2020 02:42:50
User entered 'None (1)'	System	22 Sep 2020 02:42:50

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:48', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'e1f1b91a-7528-4b77-bfcc-ae0bedb2d2ad' User entered '21 Sep 2020 22:42'	System	22 Sep 2020 02:42:50
	System	22 Sep 2020 02:42:50

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 5'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:43', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'aa075c0b-57e3-48a9-9fd6-f6bcb570d955'	System	23 Sep 2020 11:42:57
User entered 'None (1)'	System	23 Sep 2020 11:42:57

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:46', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'aa075c0b-57e3-48a9-9fd6-f6bcb570d955'	System	23 Sep 2020 11:42:57
User entered 'No (N)'	System	23 Sep 2020 11:42:57

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:49', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'aa075c0b-57e3-48a9-9fd6-f6bcb570d955'	System	23 Sep 2020 11:42:57
User entered 'No (N)'	System	23 Sep 2020 11:42:57

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:53', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'aa075c0b-57e3-48a9-9fd6-f6bcb570d955'	System	23 Sep 2020 11:42:57
User entered 'None (1)'	System	23 Sep 2020 11:42:57

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:42:56', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'aa075c0b-57e3-48a9-9fd6-f6bcb570d955' User entered '23 Sep 2020 07:42'	System	23 Sep 2020 11:42:57
	System	23 Sep 2020 11:42:57

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 6'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:26', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b3abd35f-9d25-40ee-b2ff-c30a5343414a'	System	24 Sep 2020 02:06:37
User entered 'None (1)'	System	24 Sep 2020 02:06:37

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:29', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b3abd35f-9d25-40ee-b2ff-c30a5343414a'	System	24 Sep 2020 02:06:37
User entered 'No (N)'	System	24 Sep 2020 02:06:37

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:31', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b3abd35f-9d25-40ee-b2ff-c30a5343414a' User entered 'No (N)'	System	24 Sep 2020 02:06:37
	System	24 Sep 2020 02:06:37

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:33', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b3abd35f-9d25-40ee-b2ff-c30a5343414a'	System	24 Sep 2020 02:06:37
User entered 'None (1)'	System	24 Sep 2020 02:06:37

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b3abd35f-9d25-40ee-b2ff-c30a5343414a' User entered '23 Sep 2020 22:06'	System	24 Sep 2020 02:06:37
	System	24 Sep 2020 02:06:37

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 7'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:00:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd711d92d-6b96-496d-ada7-0175ef906634'	System	25 Sep 2020 12:01:11
User entered 'None (1)'	System	25 Sep 2020 12:01:11

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:00:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd711d92d-6b96-496d-ada7-0175ef906634' User entered 'No (N)'	System	25 Sep 2020 12:01:11
	System	25 Sep 2020 12:01:11

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd711d92d-6b96-496d-ada7-0175ef906634'	System	25 Sep 2020 12:01:11
User entered 'No (N)'	System	25 Sep 2020 12:01:11

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:05', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd711d92d-6b96-496d-ada7-0175ef906634'	System	25 Sep 2020 12:01:11
User entered 'None (1)'	System	25 Sep 2020 12:01:11

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:08', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd711d92d-6b96-496d-ada7-0175ef906634' User entered '25 Sep 2020 08:01'	System	25 Sep 2020 12:01:11
	System	25 Sep 2020 12:01:11

US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:05', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '51a9ae5d-b0aa-4d8a-abba-d197b6e058fd' User entered 'None (0)'	System	18 Sep 2020 18:16:27
	System	18 Sep 2020 18:16:27

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:08', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '51a9ae5d-b0aa-4d8a-abba-d197b6e058fd' User entered 'None (0)'	System	18 Sep 2020 18:16:27
	System	18 Sep 2020 18:16:27

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:11', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '51a9ae5d-b0aa-4d8a-abba-d197b6e058fd' User entered 'None (0)'	System	18 Sep 2020 18:16:27
	System	18 Sep 2020 18:16:27

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:13', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '51a9ae5d-b0aa-4d8a-abba-d197b6e058fd' User entered 'None (0)'	System	18 Sep 2020 18:16:27
	System	18 Sep 2020 18:16:27

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:16', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '51a9ae5d-b0aa-4d8a-abba-d197b6e058fd' User entered 'None (0)'	System	18 Sep 2020 18:16:27
	System	18 Sep 2020 18:16:27

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:18', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '51a9ae5d-b0aa-4d8a-abba-d197b6e058fd' User entered 'None (0)'	System	18 Sep 2020 18:16:27
	System	18 Sep 2020 18:16:27



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:21', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '51a9ae5d-b0aa-4d8a-abba-d197b6e058fd' User entered 'No (N)'	System	18 Sep 2020 18:16:27
	System	18 Sep 2020 18:16:27

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-18T14:16:23', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '51a9ae5d-b0aa-4d8a-abba-d197b6e058fd' User entered '18 Sep 2020 14:16'	System	18 Sep 2020 18:16:27
	System	18 Sep 2020 18:16:27

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 14:15'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 16:45'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:38', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '812f9c9f-afa2-45f1-ba3a-ce78d97faf10'	System	19 Sep 2020 11:26:57
User entered 'None (0)'	System	19 Sep 2020 11:26:57

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '812f9c9f-afa2-45f1-ba3a-ce78d97faf10'	System	19 Sep 2020 11:26:57
User entered 'None (0)'	System	19 Sep 2020 11:26:57

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:43', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '812f9c9f-afa2-45f1-ba3a-ce78d97faf10'	System	19 Sep 2020 11:26:57
User entered 'None (0)'	System	19 Sep 2020 11:26:57



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:47', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '812f9c9f-afa2-45f1-ba3a-ce78d97faf10' User entered 'None (0)'	System	19 Sep 2020 11:26:57
	System	19 Sep 2020 11:26:57

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:49', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '812f9c9f-afa2-45f1-ba3a-ce78d97faf10'	System	19 Sep 2020 11:26:57
User entered 'None (0)'	System	19 Sep 2020 11:26:57

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:51', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '812f9c9f-afa2-45f1-ba3a-ce78d97faf10'	System	19 Sep 2020 11:26:57
User entered 'None (0)'	System	19 Sep 2020 11:26:57

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:54', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '812f9c9f-afa2-45f1-ba3a-ce78d97faf10'	System	19 Sep 2020 11:26:57
User entered 'No (N)'	System	19 Sep 2020 11:26:57

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-19T07:26:56', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '812f9c9f-afa2-45f1-ba3a-ce78d97faf10' User entered '19 Sep 2020 07:26'	System	19 Sep 2020 11:26:57
	System	19 Sep 2020 11:26:57

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '18 Sep 2020 17:40'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 2'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:29', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '386bad53-bb48-402b-9066-ab827dffffd9' User entered 'None (0)'	System	20 Sep 2020 04:04:49
	System	20 Sep 2020 04:04:49

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:31', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '386bad53-bb48-402b-9066-ab827dffffd9' User entered 'None (0)'	System	20 Sep 2020 04:04:49
	System	20 Sep 2020 04:04:49

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:33', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '386bad53-bb48-402b-9066-ab827dffffd9' User entered 'None (0)'	System	20 Sep 2020 04:04:49
	System	20 Sep 2020 04:04:49

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '386bad53-bb48-402b-9066-ab827fdfffd9' User entered 'None (0)'	System	20 Sep 2020 04:04:49
	System	20 Sep 2020 04:04:49

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:37', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '386bad53-bb48-402b-9066-ab827dffffd9' User entered 'None (0)'	System	20 Sep 2020 04:04:49
	System	20 Sep 2020 04:04:49

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '386bad53-bb48-402b-9066-ab827dffffd9' User entered 'None (0)'	System	20 Sep 2020 04:04:49
	System	20 Sep 2020 04:04:49

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:43', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '386bad53-bb48-402b-9066-ab827fdfff9'	System	20 Sep 2020 04:04:49
User entered 'No (N)'	System	20 Sep 2020 04:04:49

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T00:04:46', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '386bad53-bb48-402b-9066-ab827dffffd9' User entered '20 Sep 2020 00:04'	System	20 Sep 2020 04:04:49
	System	20 Sep 2020 04:04:49



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 3'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:53', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9e034161-a954-42a3-b91e-10882a5d8998'	System	20 Sep 2020 22:14:09
User entered 'None (0)'	System	20 Sep 2020 22:14:09

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9e034161-a954-42a3-b91e-10882a5d8998'	System	20 Sep 2020 22:14:09
User entered 'None (0)'	System	20 Sep 2020 22:14:09

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:57', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9e034161-a954-42a3-b91e-10882a5d8998'	System	20 Sep 2020 22:14:09
User entered 'None (0)'	System	20 Sep 2020 22:14:09

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:13:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9e034161-a954-42a3-b91e-10882a5d8998' User entered 'None (0)'	System	20 Sep 2020 22:14:09
	System	20 Sep 2020 22:14:09

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:14:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9e034161-a954-42a3-b91e-10882a5d8998'	System	20 Sep 2020 22:14:09
User entered 'None (0)'	System	20 Sep 2020 22:14:09



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:14:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9e034161-a954-42a3-b91e-10882a5d8998'	System	20 Sep 2020 22:14:09
User entered 'None (0)'	System	20 Sep 2020 22:14:09

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:14:05', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9e034161-a954-42a3-b91e-10882a5d8998'	System	20 Sep 2020 22:14:09
User entered 'No (N)'	System	20 Sep 2020 22:14:09

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-20T18:14:08', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9e034161-a954-42a3-b91e-10882a5d8998' User entered '20 Sep 2020 18:14'	System	20 Sep 2020 22:14:09
	System	20 Sep 2020 22:14:09

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 4'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:52', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '42bbafa0-a748-4ef2-9801-efb5954ae0eb' User entered 'None (0)'	System	22 Sep 2020 02:43:14
	System	22 Sep 2020 02:43:14

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '42bbafa0-a748-4ef2-9801-efb5954ae0eb' User entered 'None (0)'	System	22 Sep 2020 02:43:14
	System	22 Sep 2020 02:43:14



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:57', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '42bbafa0-a748-4ef2-9801-efb5954ae0eb' User entered 'None (0)'	System	22 Sep 2020 02:43:14
	System	22 Sep 2020 02:43:14

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:42:59', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '42bbafa0-a748-4ef2-9801-efb5954ae0eb' User entered 'None (0)'	System	22 Sep 2020 02:43:14
	System	22 Sep 2020 02:43:14

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:43:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '42bbafa0-a748-4ef2-9801-efb5954ae0eb' User entered 'None (0)'	System	22 Sep 2020 02:43:14
	System	22 Sep 2020 02:43:14

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:43:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '42bbafa0-a748-4ef2-9801-efb5954ae0eb' User entered 'None (0)'	System	22 Sep 2020 02:43:14
	System	22 Sep 2020 02:43:14

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:43:06', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '42bbafa0-a748-4ef2-9801-efb5954ae0eb' User entered 'No (N)'	System	22 Sep 2020 02:43:14
	System	22 Sep 2020 02:43:14

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-21T22:43:09', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '42bbafa0-a748-4ef2-9801-efb5954ae0eb' User entered '21 Sep 2020 22:43'	System	22 Sep 2020 02:43:14
	System	22 Sep 2020 02:43:14

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 5'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:43:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9b08390d-79e1-4cc0-a2e6-a88a8c1d584d' User entered 'None (0)'	System	23 Sep 2020 11:43:22
	System	23 Sep 2020 11:43:22

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:43:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9b08390d-79e1-4cc0-a2e6-a88a8c1d584d' User entered 'None (0)'	System	23 Sep 2020 11:43:22
	System	23 Sep 2020 11:43:22

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:43:06', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9b08390d-79e1-4cc0-a2e6-a88a8c1d584d' User entered 'None (0)'	System	23 Sep 2020 11:43:22
	System	23 Sep 2020 11:43:22

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:43:09', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9b08390d-79e1-4cc0-a2e6-a88a8c1d584d' User entered 'None (0)'	System	23 Sep 2020 11:43:22
	System	23 Sep 2020 11:43:22

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:43:12', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9b08390d-79e1-4cc0-a2e6-a88a8c1d584d' User entered 'None (0)'	System	23 Sep 2020 11:43:22
	System	23 Sep 2020 11:43:22

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:43:14', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9b08390d-79e1-4cc0-a2e6-a88a8c1d584d' User entered 'None (0)'	System	23 Sep 2020 11:43:22
	System	23 Sep 2020 11:43:22

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:43:17', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9b08390d-79e1-4cc0-a2e6-a88a8c1d584d' User entered 'No (N)'	System	23 Sep 2020 11:43:22
	System	23 Sep 2020 11:43:22



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T07:43:20', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9b08390d-79e1-4cc0-a2e6-a88a8c1d584d' User entered '23 Sep 2020 07:43'	System	23 Sep 2020 11:43:22
	System	23 Sep 2020 11:43:22

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 6'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:40', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f61208ff-56d1-4f59-895d-63a1bf1434c9' User entered 'None (0)'	System	24 Sep 2020 02:06:58
	System	24 Sep 2020 02:06:58

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:42', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f61208ff-56d1-4f59-895d-63a1bf1434c9' User entered 'None (0)'	System	24 Sep 2020 02:06:58
	System	24 Sep 2020 02:06:58

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:44', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f61208ff-56d1-4f59-895d-63a1bf1434c9' User entered 'None (0)'	System	24 Sep 2020 02:06:58
	System	24 Sep 2020 02:06:58

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:46', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f61208ff-56d1-4f59-895d-63a1bf1434c9' User entered 'None (0)'	System	24 Sep 2020 02:06:58
	System	24 Sep 2020 02:06:58



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:48', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f61208ff-56d1-4f59-895d-63a1bf1434c9' User entered 'None (0)'	System	24 Sep 2020 02:06:58
	System	24 Sep 2020 02:06:58

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:50', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f61208ff-56d1-4f59-895d-63a1bf1434c9' User entered 'None (0)'	System	24 Sep 2020 02:06:58
	System	24 Sep 2020 02:06:58

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:53', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f61208ff-56d1-4f59-895d-63a1bf1434c9'	System	24 Sep 2020 02:06:58
User entered 'No (N)'	System	24 Sep 2020 02:06:58

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-23T22:06:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f61208ff-56d1-4f59-895d-63a1bf1434c9' User entered '23 Sep 2020 22:06'	System	24 Sep 2020 02:06:58
	System	24 Sep 2020 02:06:58

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
Data entry locked.	System	18 Sep 2020 17:57:32
User entered 'Day 7'	System	18 Sep 2020 17:57:32

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:12', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4e5d2dd3-eb8a-499f-8cc1-7ce0a9b92c2e' User entered 'None (0)'	System	25 Sep 2020 12:01:33
	System	25 Sep 2020 12:01:33



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:14', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4e5d2dd3-eb8a-499f-8cc1-7ce0a9b92c2e' User entered 'None (0)'	System	25 Sep 2020 12:01:33
	System	25 Sep 2020 12:01:33

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:17', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4e5d2dd3-eb8a-499f-8cc1-7ce0a9b92c2e' User entered 'None (0)'	System	25 Sep 2020 12:01:33
	System	25 Sep 2020 12:01:33

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4e5d2dd3-eb8a-499f-8cc1-7ce0a9b92c2e' User entered 'None (0)'	System	25 Sep 2020 12:01:33
	System	25 Sep 2020 12:01:33

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:21', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4e5d2dd3-eb8a-499f-8cc1-7ce0a9b92c2e' User entered 'None (0)'	System	25 Sep 2020 12:01:33
	System	25 Sep 2020 12:01:33

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:23', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4e5d2dd3-eb8a-499f-8cc1-7ce0a9b92c2e' User entered 'None (0)'	System	25 Sep 2020 12:01:33
	System	25 Sep 2020 12:01:33

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

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 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:26', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4e5d2dd3-eb8a-499f-8cc1-7ce0a9b92c2e' User entered 'No (N)'	System	25 Sep 2020 12:01:33
	System	25 Sep 2020 12:01:33

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-09-25T08:01:29', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '4e5d2dd3-eb8a-499f-8cc1-7ce0a9b92c2e' User entered '25 Sep 2020 08:01'	System	25 Sep 2020 12:01:33
	System	25 Sep 2020 12:01:33

US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:57:32



US3302327

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:12:12

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:51
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:57:32

US3302327

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:25:20
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	25 Sep 2020 18:17:03

US3302327

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:25:20
User entered '25 Sep 2020'	Wendy Taylor (b) (4)	25 Sep 2020 18:17:03

US3302327

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:25:20
User entered 'Contact Made (CONTACT MADE)'	Wendy Taylor (b) (4)	25 Sep 2020 18:17:03

US3302327

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:25:20
User entered empty.	Wendy Taylor (b) (4)	25 Sep 2020 18:17:03

US3302327

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:25:24
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	25 Sep 2020 18:17:06

US3302327

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	25 Sep 2020 18:17:06

US3302327

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:36:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:33:29



US3302327

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:36:10
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 14:33:29

US3302327

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:36:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 14:33:29

US3302327

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:36:10
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 14:33:29

US3302327

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:36:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 14:33:21

US3302327

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	02 Oct 2020 14:33:21

US3302327

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:29:31

US3302327

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:37:20
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 17:29:31

US3302327

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 17:29:31



US3302327

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:37:20
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:29:31

US3302327

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:29:24

US3302327

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	09 Oct 2020 17:29:24

US3302327

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:52
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:27

US3302327

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:52
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:27

US3302327

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:37:52
User entered 'Clinic (Clinic)'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:27

US3302327

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'VISIT3'	System	19 Oct 2020 13:39:27

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47



US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered '08:20'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '19 Oct 2020 08:20'	System	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered '97.8' F	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered 'Oral (Oral)'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered empty.	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered '85'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'bpm'	System	19 Oct 2020 13:39:47



US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered '16'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'breaths/min'	System	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered '108'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:27
User entered '73'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered 'mmHg'	System	19 Oct 2020 13:39:47

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35

US3302327

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35



US3302327

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:41
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:53

US3302327

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:38:41
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 13:39:53

US3302327

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:03
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 13:40:00

US3302327

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:03
User entered '19 Oct 2020'	Brittany Belcher (b) (4)	19 Oct 2020 13:40:00

US3302327

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:03
User entered '08:22'	Brittany Belcher (b) (4)	19 Oct 2020 13:40:00

US3302327

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '19 Oct 2020 08:22'	System	19 Oct 2020 13:40:00

US3302327

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:41:09
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	19 Oct 2020 13:40:03

US3302327

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	19 Oct 2020 13:40:03



US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 64'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-10-21T08:01:51', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '80354a74-c2ca-4576-b146-6f06ca5d01e5'	System	21 Oct 2020 12:02:13
User entered 'No (N)'	System	21 Oct 2020 12:02:13

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-10-21T08:00:51', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '80354a74-c2ca-4576-b146-6f06ca5d01e5'	System	21 Oct 2020 12:02:13
User entered 'Yes (Y)'	System	21 Oct 2020 12:02:13

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Please 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)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-10-21T08:01:06', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '80354a74-c2ca-4576-b146-6f06ca5d01e5'	System	21 Oct 2020 12:02:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 12:02:13

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-10-21T08:02:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '80354a74-c2ca-4576-b146-6f06ca5d01e5' User entered '21 Oct 2020 08:02:01'	System	21 Oct 2020 12:02:13
	System	21 Oct 2020 12:02:13

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 71'	System	21 Aug 2020 19:51:37



US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-10-28T08:52:04', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '267b9827-1b34-42ce-b686-5b83404b7ee9'	System	28 Oct 2020 12:52:19
User entered 'No (N)'	System	28 Oct 2020 12:52:19

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-10-28T08:52:10', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '267b9827-1b34-42ce-b686-5b83404b7ee9'	System	28 Oct 2020 12:52:19
User entered 'No (N)'	System	28 Oct 2020 12:52:19

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-10-28T08:52:15', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '267b9827-1b34-42ce-b686-5b83404b7ee9' User entered '28 Oct 2020 08:52:15'	System	28 Oct 2020 12:52:19
	System	28 Oct 2020 12:52:19

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 78'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-05T00:10:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '63353228-c679-4b5d-963b-9708de9cfd9f' User entered 'No (N)'	System	05 Nov 2020 05:10:16
	System	05 Nov 2020 05:10:16

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-05T00:10:09', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '63353228-c679-4b5d-963b-9708de9cfd9f' User entered 'No (N)'	System	05 Nov 2020 05:10:16
	System	05 Nov 2020 05:10:16



US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-05T00:10:13', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '63353228-c679-4b5d-963b-9708de9cfd9f' User entered '05 Nov 2020 00:10:13'	System	05 Nov 2020 05:10:16
	System	05 Nov 2020 05:10:16

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered 'Day 92'	System	21 Aug 2020 19:51:37

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-18T08:26:47', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '167fbc50-f703-4dc5-b560-96b0e48d0797'	System	18 Nov 2020 13:27:03
User entered 'No (N)'	System	18 Nov 2020 13:27:03

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-18T08:26:57', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '167fbc50-f703-4dc5-b560-96b0e48d0797'	System	18 Nov 2020 13:27:03
User entered 'No (N)'	System	18 Nov 2020 13:27:03

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-18T08:27:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '167fbc50-f703-4dc5-b560-96b0e48d0797' User entered '18 Nov 2020 08:27:01'	System	18 Nov 2020 13:27:03
	System	18 Nov 2020 13:27:03

US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 19:51:37



US3302327

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:23:54
Data entry locked.	System	21 Aug 2020 19:51:37
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 19:51:37

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-25T09:39:07', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3befc8b7-01ba-46a6-84df-4024b143ca9e' User entered 'No (N)'	System	25 Nov 2020 14:39:21
	System	25 Nov 2020 14:39:21

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-25T09:39:12', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3befc8b7-01ba-46a6-84df-4024b143ca9e'	System	25 Nov 2020 14:39:21
User entered 'No (N)'	System	25 Nov 2020 14:39:21

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-25T09:39:15', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3befc8b7-01ba-46a6-84df-4024b143ca9e' User entered '25 Nov 2020 09:39:15'	System	25 Nov 2020 14:39:21
	System	25 Nov 2020 14:39:21

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-29T09:28:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '456686c7-a8f6-4515-84bf-520ab33adf33'	System	29 Nov 2020 14:28:39
User entered 'No (N)'	System	29 Nov 2020 14:28:39

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-29T09:28:34', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '456686c7-a8f6-4515-84bf-520ab33adf33'	System	29 Nov 2020 14:28:39
User entered 'No (N)'	System	29 Nov 2020 14:28:39

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-11-29T09:28:37', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '456686c7-a8f6-4515-84bf-520ab33adf33'	System	29 Nov 2020 14:28:39
User entered '29 Nov 2020 09:28:37'	System	29 Nov 2020 14:28:39

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-06T07:47:08', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b632b17c-e222-4ec4-8057-3489589eb3fd' User entered 'No (N)'	System	06 Dec 2020 12:47:17
	System	06 Dec 2020 12:47:17

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-06T07:47:12', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b632b17c-e222-4ec4-8057-3489589eb3fd'	System	06 Dec 2020 12:47:17
User entered 'No (N)'	System	06 Dec 2020 12:47:17



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-06T07:47:15', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'b632b17c-e222-4ec4-8057-3489589eb3fd' User entered '06 Dec 2020 07:47:15'	System	06 Dec 2020 12:47:17
	System	06 Dec 2020 12:47:17

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-13T09:16:57', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'eb9633bc-8946-48b5-8970-e6eb716d0aaf'	System	13 Dec 2020 14:17:06
User entered 'No (N)'	System	13 Dec 2020 14:17:06

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-13T09:17:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'eb9633bc-8946-48b5-8970-e6eb716d0aaf'	System	13 Dec 2020 14:17:06
User entered 'No (N)'	System	13 Dec 2020 14:17:06

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-13T09:17:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'eb9633bc-8946-48b5-8970-e6eb716d0aaf' User entered '13 Dec 2020 09:17:03'	System	13 Dec 2020 14:17:06
	System	13 Dec 2020 14:17:06

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-20T09:52:27', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'c9f37b1e-64f2-4a61-bd57-3683d8fe5889'	System	20 Dec 2020 14:52:34
User entered 'No (N)'	System	20 Dec 2020 14:52:34

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-20T09:52:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'c9f37b1e-64f2-4a61-bd57-3683d8fe5889'	System	20 Dec 2020 14:52:34
User entered 'No (N)'	System	20 Dec 2020 14:52:34

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-20T09:52:32', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'c9f37b1e-64f2-4a61-bd57-3683d8fe5889' User entered '20 Dec 2020 09:52:32'	System	20 Dec 2020 14:52:34
	System	20 Dec 2020 14:52:34

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-28T12:48:13', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '73ec64f5-1c1c-47f4-a021-327f8f49f38c'	System	28 Dec 2020 17:48:40
User entered 'No (N)'	System	28 Dec 2020 17:48:40

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-28T12:48:18', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '73ec64f5-1c1c-47f4-a021-327f8f49f38c'	System	28 Dec 2020 17:48:40
User entered 'No (N)'	System	28 Dec 2020 17:48:40

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2020-12-28T12:48:37', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '73ec64f5-1c1c-47f4-a021-327f8f49f38c' User entered '28 Dec 2020 12:48:37'	System	28 Dec 2020 17:48:40
	System	28 Dec 2020 17:48:40

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-03T10:54:02', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '25e372d0-aecb-4d42-a29d-2f8b473d9dc0'	System	03 Jan 2021 15:54:13
User entered 'No (N)'	System	03 Jan 2021 15:54:13

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-03T10:54:05', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '25e372d0-aecb-4d42-a29d-2f8b473d9dc0'	System	03 Jan 2021 15:54:13
User entered 'No (N)'	System	03 Jan 2021 15:54:13



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-03T10:54:09', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '25e372d0-aecb-4d42-a29d-2f8b473d9dc0' User entered '03 Jan 2021 10:54:09'	System	03 Jan 2021 15:54:13
	System	03 Jan 2021 15:54:13

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-10T08:31:29', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a75e43f8-0af9-40df-a64f-5ecb2fee9de3'	System	10 Jan 2021 13:31:38
User entered 'No (N)'	System	10 Jan 2021 13:31:38

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-10T08:31:32', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a75e43f8-0af9-40df-a64f-5ecb2fee9de3'	System	10 Jan 2021 13:31:38
User entered 'No (N)'	System	10 Jan 2021 13:31:38

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-10T08:31:35', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a75e43f8-0af9-40df-a64f-5ecb2fee9de3' User entered '10 Jan 2021 08:31:35'	System	10 Jan 2021 13:31:38
	System	10 Jan 2021 13:31:38

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-18T12:38:01', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '14178933-fa54-4bf9-a74b-6e201238382b' User entered 'No (N)'	System	18 Jan 2021 17:38:26
	System	18 Jan 2021 17:38:26

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-18T12:38:09', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '14178933-fa54-4bf9-a74b-6e201238382b' User entered 'No (N)'	System	18 Jan 2021 17:38:26
	System	18 Jan 2021 17:38:26

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-18T12:38:21', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '14178933-fa54-4bf9-a74b-6e201238382b' User entered '18 Jan 2021 12:38:21'	System	18 Jan 2021 17:38:26
	System	18 Jan 2021 17:38:26

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-24T00:01:25', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a910c0c-3e16-499b-a239-5000af5d6403'	System	24 Jan 2021 05:01:51
User entered 'No (N)'	System	24 Jan 2021 05:01:51

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-24T00:01:27', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a910c0c-3e16-499b-a239-5000af5d6403'	System	24 Jan 2021 05:01:51
User entered 'No (N)'	System	24 Jan 2021 05:01:51

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-24T00:01:30', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3a910c0c-3e16-499b-a239-5000af5d6403' User entered '24 Jan 2021 00:01:30'	System	24 Jan 2021 05:01:51
	System	24 Jan 2021 05:01:51

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-31T07:27:51', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '036fdc47-4648-455c-8947-7a8b9d7cca29'	System	31 Jan 2021 12:28:05
User entered 'No (N)'	System	31 Jan 2021 12:28:05

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-31T07:28:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '036fdc47-4648-455c-8947-7a8b9d7cca29' User entered 'No (N)'	System	31 Jan 2021 12:28:05
	System	31 Jan 2021 12:28:05



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-01-31T07:28:02', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '036fdc47-4648-455c-8947-7a8b9d7cca29' User entered '31 Jan 2021 07:28:02'	System	31 Jan 2021 12:28:05
	System	31 Jan 2021 12:28:05

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-07T08:27:49', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3cb62606-d8ac-4623-991b-1ef90638b4a3'	System	07 Feb 2021 13:28:03
User entered 'No (N)'	System	07 Feb 2021 13:28:03

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-07T08:27:55', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3cb62606-d8ac-4623-991b-1ef90638b4a3'	System	07 Feb 2021 13:28:03
User entered 'No (N)'	System	07 Feb 2021 13:28:03

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-07T08:27:58', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '3cb62606-d8ac-4623-991b-1ef90638b4a3' User entered '07 Feb 2021 08:27:58'	System	07 Feb 2021 13:28:03
	System	07 Feb 2021 13:28:03

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-14T09:05:13', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'cc3c4650-ab31-4cc3-8b59-40a1fc469d04'	System	14 Feb 2021 14:06:14
User entered 'Yes (Y)'	System	14 Feb 2021 14:06:14

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-14T09:05:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'cc3c4650-ab31-4cc3-8b59-40a1fc469d04'	System	14 Feb 2021 14:06:14
User entered 'No (N)'	System	14 Feb 2021 14:06:14

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-14T09:05:24', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'cc3c4650-ab31-4cc3-8b59-40a1fc469d04'	System	14 Feb 2021 14:06:14
User entered 'No (N)'	System	14 Feb 2021 14:06:14

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-14T09:05:33', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'cc3c4650-ab31-4cc3-8b59-40a1fc469d04'	System	14 Feb 2021 14:06:14
User entered 'Yes (Y)'	System	14 Feb 2021 14:06:14

US3302327

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:12:12**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-14T09:05:53', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'cc3c4650-ab31-4cc3-8b59-40a1fc469d04'	System	14 Feb 2021 14:06:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 14:06:14

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-14T09:06:03', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'cc3c4650-ab31-4cc3-8b59-40a1fc469d04' User entered '14 Feb 2021 09:06:03'	System	14 Feb 2021 14:06:14
	System	14 Feb 2021 14:06:14



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-22T11:38:14', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0a1e20ef-4c9c-4b30-937d-0bf0ed4b3480'	System	22 Feb 2021 16:38:21
User entered 'No (N)'	System	22 Feb 2021 16:38:21

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-22T11:38:17', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0a1e20ef-4c9c-4b30-937d-0bf0ed4b3480'	System	22 Feb 2021 16:38:21
User entered 'No (N)'	System	22 Feb 2021 16:38:21

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-22T11:38:19', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '0a1e20ef-4c9c-4b30-937d-0bf0ed4b3480'	System	22 Feb 2021 16:38:21
User entered '22 Feb 2021 11:38:19'	System	22 Feb 2021 16:38:21

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-28T08:10:48-05:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '96b69299-df52-494e-9ee1-f5c2c484ed1c'	System	28 Feb 2021 13:11:03
User entered 'No (N)'	System	28 Feb 2021 13:11:03

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-28T08:10:55-05:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '96b69299-df52-494e-9ee1-f5c2c484ed1c'	System	28 Feb 2021 13:11:03
User entered 'No (N)'	System	28 Feb 2021 13:11:03

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-28T08:10:58-05:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '96b69299-df52-494e-9ee1-f5c2c484ed1c' User entered '28 Feb 2021 13:10:58'	System	28 Feb 2021 13:11:03
	System	28 Feb 2021 13:11:03

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-07T08:44:25-05:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '241335f0-cdc4-481b-abc6-3cb5d0b6fae3'	System	07 Mar 2021 13:44:35
User entered 'No (N)'	System	07 Mar 2021 13:44:35



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-07T08:44:28-05:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '241335f0-cdc4-481b-abc6-3cb5d0b6fae3'	System	07 Mar 2021 13:44:35
User entered 'No (N)'	System	07 Mar 2021 13:44:35

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-07T08:44:31-05:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '241335f0-cdc4-481b-abc6-3cb5d0b6fae3' User entered '07 Mar 2021 08:44:31'	System	07 Mar 2021 13:44:35
	System	07 Mar 2021 13:44:35

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-15T15:28:42-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '859f7821-c1b9-4b40-b7b2-da913edc79a0'	System	15 Mar 2021 19:28:51
User entered 'No (N)'	System	15 Mar 2021 19:28:51

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-15T15:28:45-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '859f7821-c1b9-4b40-b7b2-da913edc79a0'	System	15 Mar 2021 19:28:51
User entered 'No (N)'	System	15 Mar 2021 19:28:51

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-15T15:28:48-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '859f7821-c1b9-4b40-b7b2-da913edc79a0' User entered '15 Mar 2021 15:28:48'	System	15 Mar 2021 19:28:51
	System	15 Mar 2021 19:28:51



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-21T08:53:00-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '35b96b38-da67-4508-ac04-2c59499e2a2c' User entered 'No (N)'	System	21 Mar 2021 12:53:12
	System	21 Mar 2021 12:53:12

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-21T08:53:04-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '35b96b38-da67-4508-ac04-2c59499e2a2c'	System	21 Mar 2021 12:53:12
User entered 'No (N)'	System	21 Mar 2021 12:53:12

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-21T08:53:07-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '35b96b38-da67-4508-ac04-2c59499e2a2c' User entered '21 Mar 2021 08:53:07'	System	21 Mar 2021 12:53:12
	System	21 Mar 2021 12:53:12

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-28T08:49:09-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '54986995-e91e-4cea-b38f-a7763a72b960'	System	28 Mar 2021 12:49:19
User entered 'No (N)'	System	28 Mar 2021 12:49:19

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-28T08:49:12-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '54986995-e91e-4cea-b38f-a7763a72b960' User entered 'No (N)'	System	28 Mar 2021 12:49:19
	System	28 Mar 2021 12:49:19

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-03-28T08:49:15-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '54986995-e91e-4cea-b38f-a7763a72b960' User entered '28 Mar 2021 08:49:15'	System	28 Mar 2021 12:49:19
	System	28 Mar 2021 12:49:19

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-05T08:14:30-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'fa156f81-1505-4ad0-8542-39e25cc7f081'	System	05 Apr 2021 12:14:40
User entered 'No (N)'	System	05 Apr 2021 12:14:40



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-05T08:14:34-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'fa156f81-1505-4ad0-8542-39e25cc7f081'	System	05 Apr 2021 12:14:40
User entered 'No (N)'	System	05 Apr 2021 12:14:40

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-05T08:14:36-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'fa156f81-1505-4ad0-8542-39e25cc7f081'	System	05 Apr 2021 12:14:40
User entered '05 Apr 2021 08:14:36'	System	05 Apr 2021 12:14:40

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-11T07:31:53-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cb65aa2-53be-4649-a7d9-fa4677d27e0a'	System	11 Apr 2021 11:32:05
User entered 'No (N)'	System	11 Apr 2021 11:32:05

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-11T07:31:56-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cb65aa2-53be-4649-a7d9-fa4677d27e0a'	System	11 Apr 2021 11:32:05
User entered 'No (N)'	System	11 Apr 2021 11:32:05

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-11T07:32:02-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '9cb65aa2-53be-4649-a7d9-fa4677d27e0a' User entered '11 Apr 2021 07:32:02'	System	11 Apr 2021 11:32:05
	System	11 Apr 2021 11:32:05



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-18T08:07:15-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f6137a3b-7b07-4b09-a437-5b1993f8c898'	System	18 Apr 2021 12:07:23
User entered 'No (N)'	System	18 Apr 2021 12:07:23

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-18T08:07:18-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f6137a3b-7b07-4b09-a437-5b1993f8c898'	System	18 Apr 2021 12:07:23
User entered 'No (N)'	System	18 Apr 2021 12:07:23

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-18T08:07:21-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'f6137a3b-7b07-4b09-a437-5b1993f8c898'	System	18 Apr 2021 12:07:23
User entered '18 Apr 2021 08:07:21'	System	18 Apr 2021 12:07:23

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-25T07:29:29-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a3c72e10-be90-487f-878a-9fe662682ac0'	System	25 Apr 2021 11:29:38
User entered 'No (N)'	System	25 Apr 2021 11:29:38

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-25T07:29:32-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a3c72e10-be90-487f-878a-9fe662682ac0'	System	25 Apr 2021 11:29:38
User entered 'No (N)'	System	25 Apr 2021 11:29:38

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-04-25T07:29:35-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'a3c72e10-be90-487f-878a-9fe662682ac0'	System	25 Apr 2021 11:29:38
User entered '25 Apr 2021 07:29:35'	System	25 Apr 2021 11:29:38

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-05-02T07:08:26-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd1fc892e-df0d-40c8-9af4-3728dd396a53'	System	02 May 2021 11:08:35
User entered 'No (N)'	System	02 May 2021 11:08:35



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

Have you been exposed to someone with 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 (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-05-02T07:08:28-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd1fc892e-df0d-40c8-9af4-3728dd396a53'	System	02 May 2021 11:08:35
User entered 'No (N)'	System	02 May 2021 11:08:35

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-05-02T07:08:30-04:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: 'd1fc892e-df0d-40c8-9af4-3728dd396a53'	System	02 May 2021 11:08:35
User entered '02 May 2021 07:08:30'	System	02 May 2021 11:08:35

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:57:08



US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:57:08

US3302327

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:12:12

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:57:08
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:57:08

US3302327

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:12:12

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-28T08:11:10-05:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '81873ba6-e88e-4d07-bfb9-548ebaceae88'	System	28 Feb 2021 13:11:19
User entered 'No (N)'	System	28 Feb 2021 13:11:19

US3302327

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:12:12

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EB527C69-D8B5-4E9B-99C8-49952CB37874)', Time: '2021-02-28T08:11:16-05:00', User OID: 'PatientReportedOutcome (US3302327)', ODM File OID: '81873ba6-e88e-4d07-bfb9-548ebaceae88' User entered '28 Feb 2021 13:11:16'	System	28 Feb 2021 13:11:19
	System	28 Feb 2021 13:11:19

US3302327

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:32:12
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	13 Nov 2020 15:31:06

US3302327

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:32:12
User entered '13 Nov 2020'	Brittany Belcher (b) (4)	13 Nov 2020 15:31:06

US3302327

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:32:12
User entered 'Contact Made (CONTACT MADE)'	Brittany Belcher (b) (4)	13 Nov 2020 15:31:06



US3302327

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:32:12
User entered empty.	Brittany Belcher (b) (4)	13 Nov 2020 15:31:06

US3302327

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:32:16
User entered 'Yes (Y)'	Brittany Belcher (b) (4)	13 Nov 2020 15:31:11

US3302327

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:22:35
User entered '1'	System	13 Nov 2020 15:31:11

US3302327

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:33:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 14:59:23

US3302327

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:33:10
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 14:59:23

US3302327

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:33:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Dec 2020 14:59:23

US3302327

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:33:10
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 14:59:23

US3302327

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:33:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 14:59:28



US3302327

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered '1'	System	17 Dec 2020 14:59:28

US3302327

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:34:12
User entered 'Yes (Y)'	Kendal Nelson (b) (4) (b) (4)	13 Jan 2021 19:18:06

US3302327

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:34:12
User entered '13 Jan 2021'	Kendal Nelson (b) (4) (b) (4)	13 Jan 2021 19:18:06

US3302327

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:34:12
User entered 'Contact Made (CONTACT MADE)'	Kendal Nelson (b) (4) (b) (4)	13 Jan 2021 19:18:06

US3302327

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:34:12
User entered empty.	Kendal Nelson (b) (4) (b) (4)	13 Jan 2021 19:18:06

US3302327

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 23:34:18
User entered 'Yes (Y)'	Kendal Nelson (b) (4) (b) (4)	13 Jan 2021 19:17:59

US3302327

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered '1'	System	13 Jan 2021 19:17:59

US3302327

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:13:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) Kendal Nelson (b) (4)	18 Feb 2021 17:43:38



US3302327

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:13:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '18 Feb 2021'	(b) (4) Kendal Nelson (b) (4)	18 Feb 2021 17:43:38
	(b) (4)	

US3302327

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:13:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kendal Nelson (b) (4)	18 Feb 2021 17:43:38

US3302327

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:13:14
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) Kendal Nelson (b) (4)	18 Feb 2021 17:43:38
	(b) (4)	

US3302327

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:13:19
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) Kendal Nelson (b) (4)	18 Feb 2021 17:43:44
	(b) (4)	

US3302327

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered '1'	System	18 Feb 2021 17:43:44

US3302327

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User closed query 'Per the source the vitals were assessed for this visit. Kindly review the source, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 20:11:50
Query 'Per the source the vitals were assessed for this visit. Kindly review the source, and update accordingly. ' answered with 'updated. ' (Site from CRA).	Brittany Belcher (b) (4)	01 Apr 2021 17:41:55
User opened query 'Per the source the vitals were assessed for this visit. Kindly review the source, and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 15:14:08
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:13:45
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:35

US3302327

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:13:45
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:35

US3302327

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:13:45
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:35



US3302327

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered 'VISIT4'	System	23 Mar 2021 19:54:35

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered 'Yes (Y)'	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered '23 Mar 2021'	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered '08:40'	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered '23 Mar 2021 08:40'	System	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered '97.5' F	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered 'Oral (Oral)'	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered empty.	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46



US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered '88'	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered 'bpm'	System	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered '16'	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered 'breaths/min'	System	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered '108'	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered 'mmHg'	System	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:12:16
User signature succeeded.	Gregory Feldman (b) (4)	02 Apr 2021 16:01:36
User entered '71'	(b) (4) Brittany Belcher (b) (4)	01 Apr 2021 17:41:46

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered 'mmHg'	System	01 Apr 2021 17:41:46



US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05

US3302327

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05

US3302327

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:14:31
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:27

US3302327

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:14:31
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:27

US3302327

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:14:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:19

US3302327

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:14:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:19

US3302327

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:14:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '08:44'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:19

US3302327

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered '23 Mar 2021 08:44'	System	23 Mar 2021 19:54:19



US3302327

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:14:45
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:10

US3302327

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:21:05
User entered '1'	System	23 Mar 2021 19:54:10

US3302327

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:05
User entered 'Yes (Y)'	(b) (4) Kendal Nelson (b) (4)	13 Apr 2021 12:29:08
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:05
User entered '13 Apr 2021'	(b) (4) Kendal Nelson (b) (4)	13 Apr 2021 12:29:08
	(b) (4)	

US3302327

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kendal Nelson (b) (4)	13 Apr 2021 12:29:08
	(b) (4)	

US3302327

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:05
User entered empty.	(b) (4) Kendal Nelson (b) (4)	13 Apr 2021 12:29:08
	(b) (4)	

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:05
User entered 'Yes (Y)'	(b) (4) Kendal Nelson (b) (4)	13 Apr 2021 12:29:14
	(b) (4)	

US3302327

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 12:29:14

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US3302327

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:15:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:22

US3302327

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:15:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:22

US3302327

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:15:13
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:22

US3302327

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

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 21:14:22

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:17:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:50

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:19:27
User entered '0'	Brittany Belcher (b) (4)	12 Apr 2021 14:22:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:33:30

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:17:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:14:50

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
User signature succeeded.	Gregory Feldman (b) (4)	29 Apr 2021 12:34:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:19:29
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:38:59
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated. ' (Site from DM).	Brittany Belcher (b) (4)	12 Apr 2021 14:22:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brittany Belcher (b) (4)	12 Apr 2021 14:22:29
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:15:08
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:33:30



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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:17:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:50

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:17:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	26 Jan 2021 21:14:50

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:17:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	26 Jan 2021 21:14:50

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:17:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	26 Jan 2021 21:14:50

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:17:51
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 21:14:50

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered '1'	System	26 Jan 2021 21:14:50

US3302327

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

Form: Unblinding

Generated On: 11 Aug 2021 22:12:12

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:43:49
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered '1'	System	26 Jan 2021 21:14:50

US3302327

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40



US3302327

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered empty.	System	26 Jan 2021 21:15:40
DataPoint set to visible.	System	26 Jan 2021 21:14:50

US3302327

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered empty.	System	26 Jan 2021 21:15:40
DataPoint set to visible.	System	26 Jan 2021 21:14:50

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40



US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '09:07'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered '26 Jan 2021 09:07'	System	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '68'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'bpm'	System	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40



US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'breaths/min'	System	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '107'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'mmHg'	System	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '73'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'mmHg'	System	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:12:12

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered empty.	System	26 Jan 2021 21:15:40
DataPoint set to visible.	System	26 Jan 2021 21:14:50



US3302327

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '09:55'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered '26 Jan 2021 09:55'	System	26 Jan 2021 21:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '75'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'bpm'	System	26 Jan 2021 21:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'breaths/min'	System	26 Jan 2021 21:15:40

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '95'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'mmHg'	System	26 Jan 2021 21:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:28
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '71'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'mmHg'	System	26 Jan 2021 21:15:40



US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:48

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:39
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:48

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:56

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:56

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:56

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:56

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:56

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:56



US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:20:55
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:15:56

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered empty.	System	26 Jan 2021 21:15:56

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:55:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:16:06

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:55:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:16:06

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:55:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:16:06

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'mRNA-1273'	System	26 Jan 2021 21:16:06
DataPoint set to visible.	System	26 Jan 2021 21:14:50

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User closed query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:21:28
Query 'Per CDMRQ: please review date in IRT and update accordingly' answered with 'Per IWRS, data entered is correct.' (Site from DM).	Brittany Belcher (b) (4)	15 Apr 2021 16:19:46
User opened query 'Per CDMRQ: please review date in IRT and update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 16:13:42
User closed query 'Per IRT, Subject had Open Label Day1 Treatment on 27JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 16:13:42
Query 'Per IRT, Subject had Open Label Day1 Treatment on 27JAN2021. Please review and reconcile. ' answered with 'Per source, the OL Visit Day 1 occurred on 26JAN2021. Data entered is correct.' (Site from DM).	Brittany Belcher (b) (4)	12 Apr 2021 14:22:12
User opened query 'Per IRT, Subject had Open Label Day1 Treatment on 27JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:20:24
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:55:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:16:06

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:55:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '09:10'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:16:06



US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered '26 Jan 2021 09:10'	System	26 Jan 2021 21:16:06

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:55:05
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:16:06

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:55:05
User entered 'ONCE'	System	26 Jan 2021 21:16:06

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 21:16:06

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:21:30
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:31

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:21:30
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:31

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:21:30
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '08:50'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:31

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered '26 Jan 2021 08:50'	System	26 Jan 2021 21:14:31



US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:21:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:39

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:21:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:39

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:21:41
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '08:48'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:14:39

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:12:12

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered '26 Jan 2021 08:48'	System	26 Jan 2021 21:14:39

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:21:46
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 21:16:09

US3302327

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:58:40
User entered '1'	System	26 Jan 2021 21:16:09

US3302327

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:35:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	02 Feb 2021 13:35:35

US3302327

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:35:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered '2 Feb 2021'	(b) (4) Wendy Taylor (b) (4)	02 Feb 2021 13:35:35



US3302327

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:35:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	02 Feb 2021 13:35:35

US3302327

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:35:38
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered empty.	(b) (4) Wendy Taylor (b) (4)	02 Feb 2021 13:35:35

US3302327

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:02
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:35:44
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
User entered 'Yes (Y)'	Wendy Taylor (b) (4)	02 Feb 2021 13:35:41

US3302327

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:02
User entered '1'	System	02 Feb 2021 13:35:41

US3302327

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:42:02
User entered '1'	System	02 Feb 2021 13:35:41
DataPoint set to visible.	System	02 Feb 2021 13:35:41

US3302327

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:36:54
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:39:25

US3302327

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:36:54
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:39:25

US3302327

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[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 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:36:54
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:39:25



US3302327

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered 'OLD29'	System	01 Mar 2021 15:39:25

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered '09:35'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered '26 Feb 2021 09:35'	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17



US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered '83'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered 'bpm'	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered 'breaths/min'	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered '104'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered 'mmHg'	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered '66'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17



US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:12:12

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered 'mmHg'	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17



US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:15
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:17



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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:17

US3302327

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:53
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:27

US3302327

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:43:53
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:27

US3302327

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:45:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:46

US3302327

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:45:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:46

US3302327

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:45:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:46

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Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:45:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 09:38:29
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Pregnancy form sent to safety on 26FEB2021.' (Site from System).	Brittany Belcher (b) (4)	11 Mar 2021 21:24:23
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	01 Mar 2021 15:40:46
User entered 'Positive (POSITIVE)'	(b) (4), (b) (6)	01 Mar 2021 15:40:46

US3302327

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:45:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:46



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Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:45:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:46

US3302327

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:45:29
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:46

US3302327

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:46

US3302327

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:53
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:59

US3302327

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:53
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	01 Mar 2021 15:41:05
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 15:41:05
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	01 Mar 2021 15:40:59
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 15:40:59

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

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)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:53
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:59

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:59
DataPoint set to visible.	System	02 Feb 2021 13:35:41

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:53
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:59



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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:53
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:59

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:59

US3302327

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:53
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:40:59

US3302327

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:53
User entered empty.	System	01 Mar 2021 15:40:59

US3302327

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:12:12

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered empty.	System	01 Mar 2021 15:40:59

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:50:59
User signature succeeded.	Gregory Feldman (b) (4)	03 Mar 2021 18:57:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:41:10

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:50:54
User entered '1'	System	01 Mar 2021 15:41:10

US3302327

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:49
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:51:42
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:43:29
User entered 'Yes (Y)'	(b) (4) Wendy Taylor (b) (4)	05 Mar 2021 15:23:47



US3302327

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:49
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:51:42
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:43:29
User entered '05 Mar 2021'	(b) (4) Wendy Taylor (b) (4)	05 Mar 2021 15:23:47

US3302327

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:49
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:51:42
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:43:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Wendy Taylor (b) (4)	05 Mar 2021 15:23:47

US3302327

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:12:12

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:49
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:51:42
User signature succeeded.	Gregory Feldman (b) (4)	05 Mar 2021 21:43:29
User entered empty.	(b) (4) Wendy Taylor (b) (4)	05 Mar 2021 15:23:47

US3302327

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:49
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:51:57
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 14:37:49

US3302327

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:12:12

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:44:49
User entered '1'	System	23 Mar 2021 14:37:49

US3302327

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:19
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:53

US3302327

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:19
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:53

US3302327

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[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 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:19
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:54:53



US3302327

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:12:12

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
User entered 'OLD57'	System	23 Mar 2021 19:54:53

US3302327

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

US3302327

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

US3302327

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '08:40'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

US3302327

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
User entered '23 Mar 2021 08:40'	System	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11



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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '88'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
User entered 'bpm'	System	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
User entered 'breaths/min'	System	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '108'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
User entered 'mmHg'	System	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:40
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '71'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
User entered 'mmHg'	System	23 Mar 2021 19:55:11



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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:12:12

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:23

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:12:12

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:52:52
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:23

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:53:09
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:19

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:53:09
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:19

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 15:53:09
User signature succeeded.	Gregory Feldman (b) (4)	25 Mar 2021 18:20:52
User entered '08:44'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 19:55:19

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:12:12

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:25:25
User entered '23 Mar 2021 08:44'	System	23 Mar 2021 19:55:19



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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:12:12

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:35:25
Query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Per source, site contacted subject and it was reported that subject had a positive home pregnancy test. Subject also reported that she had a negative test later on 05MAR2021 at their OBGYN office. EPIP and pregnancy form has been sent. No AE to report.' (Site from DM).	Brittany Belcher (b) (4)	22 Mar 2021 13:53:03
User opened query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 03:22:57
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:46:07
User entered 'No (N)'	brittany cooksey (b) (4)	19 Nov 2020 15:01:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:12:12

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:25:05
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:24:07

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:12:12

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregory Feldman (b) (4)	19 Feb 2021 19:14:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:25:16
User entered 'No (N)'	Brittany Belcher (b) (4)	21 Aug 2020 19:24:13