

US3002329 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:52:37

All time stamps listed in this document are displayed in GMT

US3002329

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

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[Participant ID](#)

US3002329

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

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US3002329

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

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

US3002329

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Date of Birth (MMM yyyy)	(b) (6) 1987
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	HISPANIC
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:19:19

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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) 15 Feb 2021 22:19:19

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Condition	AUGMENTIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	08:16 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:16
Height (xxx.x)	153 cm
Weight (xxx.x)	75.1 kg
BMI (xxx.x)	32.08168 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Date of assessment (*dd MMM yyyy*) 28 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	28 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:19:19

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:19:19

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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) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:19:19

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What was the date of randomization? (dd MMM yyyy) 28 SEP 2020

What was the participant's randomization number? 115717

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) 15 Feb 2021 22:19:19

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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) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

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)	28 SEP 2020
Time of assessment (00:00-23:59)	08:16 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:16
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	10:03 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:03
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:19:19

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Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

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) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 09:26 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 09:26

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) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	08:51 (24 HR)
Collection date and time (derived)	28 SEP 2020 08:51



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:41	28 SEP 2020 08:41
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 09:57

PC Open Date & Time

28 SEP 2020 09:46

PC Close Date & Time

28 SEP 2020 12:16

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	28 SEP 2020 13:12
PC Open Date & Time	28 SEP 2020 13:11
PC Close Date & Time	29 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 16:58

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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

30 SEP 2020 12:03

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

01 OCT 2020 12:39

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

**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

97.2 °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

02 OCT 2020 12:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

03 OCT 2020 12:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

04 OCT 2020 12:10

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 09:57

PC Open Date & Time

28 SEP 2020 09:46

PC Close Date & Time

28 SEP 2020 12:16

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**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)

10

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

28 SEP 2020 13:15

PC Open Date & Time

28 SEP 2020 13:11

PC Close Date & Time

29 SEP 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

10

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 16:59

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 12:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 12:39

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 12:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 12:10

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**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 ☐

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 09:58
PC Open Date & Time	28 SEP 2020 09:46
PC Close Date & Time	28 SEP 2020 12:16

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**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 ☐

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 13:16
PC Open Date & Time	28 SEP 2020 13:11
PC Close Date & Time	29 SEP 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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 ☒

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 16:59
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59



US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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 ☒

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:37

		Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 12:04	
PC Open Date & Time	30 SEP 2020 12:00	
PC Close Date & Time	01 OCT 2020 11:59	

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 12:40
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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 ☒

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:37

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 ☒

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:33
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59



US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:37

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 ☒

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:10
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3002329

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002329

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002329

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002329

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002329

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002329

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3002329

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3002329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

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)	30 OCT 2020
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 08:09
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3002329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

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 (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 09:57
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3002329

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3002329

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	30 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3002329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

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) 30 OCT 2020

What was the treatment time? (00:00-23:59) 09:27 (24 HR)

Treatment Date and Time (derived) 30 OCT 2020 09:27

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

What was the frequency of the study treatment dosing? ONCE

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

US3002329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	08:47 (24 HR)
Collection date and time (derived)	30 OCT 2020 08:47

US3002329

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Collection date (dd MMM yyyy)			30 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:23	30 OCT 2020 08:23
Nasopharyngeal Swab 2	No		



US3002329

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**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 30 OCT 2020 09:59

PC Open Date & Time 30 OCT 2020 09:47

PC Close Date & Time 30 OCT 2020 12:17

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

PC Time Stamp	30 OCT 2020 13:58
PC Open Date & Time	30 OCT 2020 13:12
PC Close Date & Time	31 OCT 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**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	98.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	01 NOV 2020 10:04
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 09:35

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 12:09

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 NOV 2020 08:33

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 NOV 2020 12:00

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59



US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 NOV 2020 16:52

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 09:59

PC Open Date & Time

30 OCT 2020 09:47

PC Close Date & Time

30 OCT 2020 12:17

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**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

30 OCT 2020 14:00

PC Open Date & Time

30 OCT 2020 13:12

PC Close Date & Time

31 OCT 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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)**

5

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 10:05

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 09:35

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 12:10

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 NOV 2020 08:33

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 NOV 2020 12:01

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59



US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 NOV 2020 16:52

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**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 ☐

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

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

No ☒

Yes ☐

PC Time stamp	30 OCT 2020 09:59
PC Open Date & Time	30 OCT 2020 09:47
PC Close Date & Time	30 OCT 2020 12:17

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**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 ☐

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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

No ☒

Yes ☐

PC Time stamp	30 OCT 2020 14:00
PC Open Date & Time	30 OCT 2020 13:12
PC Close Date & Time	31 OCT 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**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 ☒

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 10:05
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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 ☒



US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 09:35
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

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 ☒

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 12:10
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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 ☒

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EAB) (1725)

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 08:34
PC Open Date & Time	03 NOV 2020 12:00
PC Close Date & Time	04 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:37

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 ☒

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	04 NOV 2020 12:01
PC Open Date & Time	04 NOV 2020 12:00
PC Close Date & Time	05 NOV 2020 11:59

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:37

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 ☒



US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Yes <input type="checkbox"/>	
PC Time stamp	05 NOV 2020 16:52
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3002329

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002329

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 04:48:29

Generated On: 11 Aug 2021 21:52:37

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*

US3002329

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002329

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002329

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3002329

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 DEC 2020
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	03 DEC 2020 10:09
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002329

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 DEC 2020

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

US3002329

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 DEC 2020
Collection time (00:00-23:59)	10:27 (24 HR)
Collection date and time (derived)	03 DEC 2020 10:27

US3002329

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 08:16:44
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 00:01:33
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 00:01:24
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 13:02:36

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59



US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 DEC 2020 09:30:40

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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	30 DEC 2020 09:05:21
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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

08 JAN 2021 09:01:18

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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	15 JAN 2021 12:19:14
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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	20 JAN 2021 00:01:54
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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	29 JAN 2021 12:21:31
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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

03 FEB 2021 00:06:24

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 11:28:01
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59



US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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

19 FEB 2021 11:18:49

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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 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	24 FEB 2021 13:07:16
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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

03 MAR 2021 10:59:41

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 13:19:13
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 00:11:29

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 16:24:09

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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

31 MAR 2021 11:19:40

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 01:23:16

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59



US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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14 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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21 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 10:38:41

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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30 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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°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 ☐

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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°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 ☐

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 NOV 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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°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 ☐

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 FEB 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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13 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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24 JUL 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JUL 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

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28 AUG 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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04 SEP 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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07 SEP 2022 00:01

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11 SEP 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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14 SEP 2022 00:01

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18 SEP 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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12 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 OCT 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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19 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59
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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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02 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 NOV 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**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 ☐

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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23 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 NOV 2022 23:59

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US3002329

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

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

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[Patient Cloud Open Date & Time](#)

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30 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 DEC 2022 23:59

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US3002329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:52:37

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		03 MAR 2021 10:59:53

US3002329

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:19:19

Generated On: 11 Aug 2021 21:52:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002329

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002329

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002329

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3002329

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 12:54:56

Generated On: 11 Aug 2021 21:52:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3002329

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 12:54:56

Generated On: 11 Aug 2021 21:52:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3002329**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

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*

**US3002329**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3002329

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:52:37

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

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3002329

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

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

Visit date (dd MMM yyyy)	28 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3002329

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 12:54:56

Generated On: 11 Aug 2021 21:52:37

Date of updated informed consent (dd MMM yyyy) 28 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 28 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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



US3002329

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00-23:59)	08:25 (24 HR)
Collection date and time (derived)	28 JAN 2021 08:25

US3002329

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	08:22
Collection Date and Time (derived)	28 JAN 2021 08:22

US3002329

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

---

Did the participant experience any adverse events?

Yes ☐

No ☒

---

If Yes, enter details on the Adverse Events form.

---

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

---

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

Yes ☒

No ☐

---

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

---

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Name of Medication LUTERA  
LEVONORGESTREL/ETHINYL  
ESTRADIOL

Prophylaxis Yes ☒  
No ☐

Indication CONTRACEPTION

Dose per administration 0.1/0.02

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

326 of 1556

EAB) (1725)

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3002329

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 22:19:18

Generated On: 11 Aug 2021 21:52:37

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3002329

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:52:37

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3002329

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:52:37

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

US3002329 (Prod: Meridian Clinical Research)

**US3002329**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:52:37**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'US3002329'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Sep 2020 13:27:54

**US3002329**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:37:47

**US3002329**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Sep 2020 13:27:55

US3002329

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:52:37

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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	28 Sep 2020 16:37:52
User entered 'Clinic (Clinic)' reason for change:	System	28 Sep 2020 16:37:52
Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 16:37:52
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).		
User entered empty.	System	28 Sep 2020 16:37:47
	(b) (4), (b) (6)	28 Sep 2020 16:37:47



**US3002329**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'SCRN'	System	28 Sep 2020 16:37:47

US3002329

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:52:37

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered (b) (6) 1987'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Sep 2020 13:27:56

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '33'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'YEARS'	System	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered '33'	System	28 Sep 2020 14:37:15

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:38:30



**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Hispanic'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:38:30

**US3002329**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:52:37**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:38:30



US3002329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:37

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:15

**US3002329**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'Sep 2020'	System	28 Sep 2020 14:37:15

**US3002329**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered '2020'	System	28 Sep 2020 14:37:15

**US3002329**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:37**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Amendment 3 (3)'	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:15

**US3002329**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:15

**US3002329**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:15

US3002329

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:52:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:15

**US3002329**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:37**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:15



**US3002329**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:37**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 13:27:55

**US3002329**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:52:37**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'I'	System	28 Sep 2020 14:37:19

US3002329

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:19

**US3002329**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 21:52:37**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:39:33

US3002329

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:52:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 16:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 16:41:45
Data point term sent to Coder	System	28 Sep 2020 16:40:28
User entered 'Penicillin allergy'	(b) (4), (b) (6)	28 Sep 2020 16:39:51

**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'un UNK 1992'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:39:51

**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:39:51

**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:39:51



**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:39:51

**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:39:51

**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'Jan 1992'	System	28 Sep 2020 16:39:51

**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered '1992'	System	28 Sep 2020 16:39:51

**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered empty.	System	28 Sep 2020 16:39:51

**US3002329**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered empty.	System	28 Sep 2020 16:39:51

US3002329

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:52:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 16:41:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 16:41:45
Data point term sent to Coder	System	28 Sep 2020 16:40:28
User entered 'Augmentin allergy'	(b) (4), (b) (6)	28 Sep 2020 16:40:03

**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:40:03



**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:40:03

**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:40:03

**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:40:03

**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:40:03

**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'Jan 2014'	System	28 Sep 2020 16:40:03

**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered '2014'	System	28 Sep 2020 16:40:03

**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered empty.	System	28 Sep 2020 16:40:03

**US3002329**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered empty.	System	28 Sep 2020 16:40:03



**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:16'	(b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered '28 Sep 2020 08:16'	System	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '153' cm	(b) (4)	28 Sep 2020 16:40:35
DataPoint set to visible.	System	28 Sep 2020 14:37:19

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '75.1' kg	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:40:35
DataPoint set to visible.	System	28 Sep 2020 14:37:19

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered '32.08168'	System	28 Sep 2020 16:40:35
DataPoint set to visible.	System	28 Sep 2020 14:37:19

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'kg/m2'	System	28 Sep 2020 16:40:35
DataPoint set to visible.	System	28 Sep 2020 14:37:19



**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'bpm'	System	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'breaths/min'	System	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:40:35



**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'mmHg'	System	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered 'mmHg'	System	28 Sep 2020 16:40:35

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26

**US3002329**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26

**US3002329**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:52:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:40:42

**US3002329**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:52:37**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 16:40:42

**US3002329**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:52:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 16:41:01



US3002329

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:41:01

**US3002329**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:41:01

**US3002329**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:52:37**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:41:01

**US3002329**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:41:01

**US3002329**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:52:37**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:01

**US3002329**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:41:01

**US3002329**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:52:37**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:41:01

**US3002329**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:09



**US3002329**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 16:41:09

**US3002329**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Urine (URINE)'	(b) (4), (b) (6)	28 Sep 2020 16:41:09

**US3002329**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:09

US3002329

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:52:37

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User closed query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 07:24:17
' (Site from DM). Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	09 Oct 2020 20:38:45
' answered with 'updated' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:38:40
User opened query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	08 Oct 2020 08:23:38
' (Site from DM). User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:41:09

**US3002329**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:41:09

**US3002329**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:41:09

**US3002329**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User entered empty.	System	28 Sep 2020 16:41:09

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19



US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

[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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

[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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

[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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:39:19



US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

**US3002329**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:52:37**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

[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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:39:19



US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

**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 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

**US3002329**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:52:37**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

**US3002329**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:52:37**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 16:39:19

US3002329

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:52:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:30:26
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 16:39:19

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:18

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:18

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:18

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'VISIT1'	System	28 Sep 2020 16:41:18



US3002329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Sep 2020 14:02:56

US3002329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:37

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '115717'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Sep 2020 14:02:56

US3002329

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:52:37

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Sep 2020 14:02:56

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:52:37**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:41:25

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:52:37**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:41:25

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:52:37**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:25

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:52:37**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:25

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:52:37**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:25



**US3002329**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:52:37**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:41:25
DataPoint set to visible.	System	28 Sep 2020 14:37:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:52:37**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:52:37**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:52:37**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:52:37**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

US3002329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15



**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '28 Sep 2020 08:16'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '72'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'bpm'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '20'	(b) (4), (b) (6)	28 Sep 2020 16:42:15



**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'breaths/min'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '127'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '88'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:52:37**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:52:37**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

US3002329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 16:42:15



US3002329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '10:03'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '28 Sep 2020 10:03'	System	28 Sep 2020 16:42:15

US3002329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '84'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15



**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'bpm'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'breaths/min'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '122'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

US3002329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '86'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:15

US3002329

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	28 Sep 2020 16:42:15

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:52:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:20



**US3002329**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:52:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:20

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:26

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:26

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:26

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:26

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:26

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:26

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:26



**US3002329**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered empty.	System	28 Sep 2020 16:42:26

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:52:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:41

US3002329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:41

US3002329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:41

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:52:37**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 14:37:41

US3002329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4) Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:41

US3002329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '09:26'	(b) (4) Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:41

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:52:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered '28 Sep 2020 09:26'	System	28 Sep 2020 14:37:41



US3002329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Left Arm (LEFT ARM)'	Tiffany Nemecek (b) (4)	28 Sep 2020 14:37:41

US3002329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'ONCE'	System	28 Sep 2020 14:37:41

US3002329

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 14:37:41

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:38

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:38

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:51'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:38

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered '28 Sep 2020 08:51'	System	28 Sep 2020 16:42:38

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:52:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:53



**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 16:42:53

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:53

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:41'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:53

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered '28 Sep 2020 08:41'	System	28 Sep 2020 16:42:53

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 16:42:53

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:53

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:53

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered empty.	System	28 Sep 2020 16:42:53



**US3002329**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:42:58

**US3002329**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'I'	System	28 Sep 2020 16:42:58

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b4732479-b75c-49a5-9515-a6fe36de7b42'	System	28 Sep 2020 14:57:15
User entered 'Yes (Y)'	System	28 Sep 2020 14:57:15

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b4732479-b75c-49a5-9515-a6fe36de7b42' User entered '98.3'	System	28 Sep 2020 14:57:15
	System	28 Sep 2020 14:57:15

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:08', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b4732479-b75c-49a5-9515-a6fe36de7b42'	System	28 Sep 2020 14:57:15
User entered 'No (N)'	System	28 Sep 2020 14:57:15

**US3002329**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:12', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b4732479-b75c-49a5-9515-a6fe36de7b42'	System	28 Sep 2020 14:57:15
User entered '28 Sep 2020 09:57'	System	28 Sep 2020 14:57:15

**US3002329**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 09:46'	System	28 Sep 2020 14:37:41



**US3002329**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 12:16'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:12:30', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '91f43f6b-e492-4fe4-9910-6d700a26cb87' User entered 'Yes (Y)'	System	28 Sep 2020 18:12:44
	System	28 Sep 2020 18:12:44

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:12:35', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '91f43f6b-e492-4fe4-9910-6d700a26cb87' User entered '98.0'	System	28 Sep 2020 18:12:44
	System	28 Sep 2020 18:12:44

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:12:37', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '91f43f6b-e492-4fe4-9910-6d700a26cb87'	System	28 Sep 2020 18:12:44
User entered 'No (N)'	System	28 Sep 2020 18:12:44

**US3002329**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:12:41', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '91f43f6b-e492-4fe4-9910-6d700a26cb87' User entered '28 Sep 2020 13:12'	System	28 Sep 2020 18:12:44
	System	28 Sep 2020 18:12:44

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 13:11'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:37:41



US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 2'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:57:20', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '86242bc8-b8e0-4828-976e-e43e0bd37f57'	System	29 Sep 2020 21:58:10
User entered 'Yes (Y)'	System	29 Sep 2020 21:58:10

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:57:59', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '86242bc8-b8e0-4828-976e-e43e0bd37f57' User entered '98.1'	System	29 Sep 2020 21:58:10
	System	29 Sep 2020 21:58:10

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:58:02', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '86242bc8-b8e0-4828-976e-e43e0bd37f57'	System	29 Sep 2020 21:58:10
User entered 'No (N)'	System	29 Sep 2020 21:58:10

**US3002329**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:58:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '86242bc8-b8e0-4828-976e-e43e0bd37f57' User entered '29 Sep 2020 16:58'	System	29 Sep 2020 21:58:10
	System	29 Sep 2020 21:58:10

**US3002329**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 3'	System	28 Sep 2020 14:37:41



US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:02:12', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '91da9bb2-799f-4261-9742-9103fe02c7c9'	System	30 Sep 2020 17:04:04
User entered 'Yes (Y)'	System	30 Sep 2020 17:04:04

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:03:15', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '91da9bb2-799f-4261-9742-9103fe02c7c9' User entered '97.4'	System	30 Sep 2020 17:04:04
	System	30 Sep 2020 17:04:04

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:03:57', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '91da9bb2-799f-4261-9742-9103fe02c7c9'	System	30 Sep 2020 17:04:04
User entered 'No (N)'	System	30 Sep 2020 17:04:04

**US3002329**

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

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:03:59', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '91da9bb2-799f-4261-9742-9103fe02c7c9' User entered '30 Sep 2020 12:03'	System	30 Sep 2020 17:04:04
	System	30 Sep 2020 17:04:04

**US3002329**

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

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 4'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:35', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e8de7fc9-5832-4b9b-b6fb-a2775af83b59'	System	01 Oct 2020 17:39:44
User entered 'Yes (Y)'	System	01 Oct 2020 17:39:44



US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:38', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e8de7fc9-5832-4b9b-b6fb-a2775af83b59'	System	01 Oct 2020 17:39:44
User entered '98.2'	System	01 Oct 2020 17:39:44

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:40', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e8de7fc9-5832-4b9b-b6fb-a2775af83b59'	System	01 Oct 2020 17:39:44
User entered 'No (N)'	System	01 Oct 2020 17:39:44

**US3002329**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:42', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e8de7fc9-5832-4b9b-b6fb-a2775af83b59'	System	01 Oct 2020 17:39:44
User entered '01 Oct 2020 12:39'	System	01 Oct 2020 17:39:44

**US3002329**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 5'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5032f86f-790d-48f5-88f8-7c811bdfa1e7'	System	02 Oct 2020 17:02:25
User entered 'Yes (Y)'	System	02 Oct 2020 17:02:25

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:37', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5032f86f-790d-48f5-88f8-7c811bdfa1e7' User entered '97.2'	System	02 Oct 2020 17:02:25
	System	02 Oct 2020 17:02:25



US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:39', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5032f86f-790d-48f5-88f8-7c811bdfa1e7'	System	02 Oct 2020 17:02:25
User entered 'No (N)'	System	02 Oct 2020 17:02:25

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:41', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5032f86f-790d-48f5-88f8-7c811bdfa1e7' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 17:02:25
	System	02 Oct 2020 17:02:25

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 6'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:28', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '117cb2d5-2165-484c-8854-2030c24fc327'	System	03 Oct 2020 17:32:38
User entered 'Yes (Y)'	System	03 Oct 2020 17:32:38

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:31', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '117cb2d5-2165-484c-8854-2030c24fc327' User entered '98.2'	System	03 Oct 2020 17:32:38
	System	03 Oct 2020 17:32:38

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '117cb2d5-2165-484c-8854-2030c24fc327'	System	03 Oct 2020 17:32:38
User entered 'No (N)'	System	03 Oct 2020 17:32:38



**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:35', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '117cb2d5-2165-484c-8854-2030c24fc327'	System	03 Oct 2020 17:32:38
User entered '03 Oct 2020 12:32'	System	03 Oct 2020 17:32:38

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 7'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:04', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fb509c96-496b-4ba7-ae0-b77df990228c' User entered 'Yes (Y)'	System	04 Oct 2020 17:10:13
	System	04 Oct 2020 17:10:13

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:07', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fb509c96-496b-4ba7-ae0-b77df990228c' User entered '98.2'	System	04 Oct 2020 17:10:13
	System	04 Oct 2020 17:10:13

US3002329

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:09', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fb509c96-496b-4ba7-ae0-b77df990228c'	System	04 Oct 2020 17:10:13
User entered 'No (N)'	System	04 Oct 2020 17:10:13

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:11', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fb509c96-496b-4ba7-ae0-b77df990228c'	System	04 Oct 2020 17:10:13
User entered '04 Oct 2020 12:10'	System	04 Oct 2020 17:10:13



**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:38', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a9526092-ff07-4e58-86bc-434b882aae96'	System	28 Sep 2020 14:57:53
User entered 'None (1)'	System	28 Sep 2020 14:57:53

**US3002329**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:41', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a9526092-ff07-4e58-86bc-434b882aae96'	System	28 Sep 2020 14:57:53
User entered 'No (N)'	System	28 Sep 2020 14:57:53

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:43', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a9526092-ff07-4e58-86bc-434b882aae96'	System	28 Sep 2020 14:57:53
User entered 'No (N)'	System	28 Sep 2020 14:57:53

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:48', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a9526092-ff07-4e58-86bc-434b882aae96'	System	28 Sep 2020 14:57:53
User entered 'None (1)'	System	28 Sep 2020 14:57:53

**US3002329**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:50', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a9526092-ff07-4e58-86bc-434b882aae96'	System	28 Sep 2020 14:57:53
User entered '28 Sep 2020 09:57'	System	28 Sep 2020 14:57:53



**US3002329**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 09:46'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 12:16'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:12:52', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e24873df-8a26-4643-b383-dd84ab832852'	System	28 Sep 2020 18:15:44
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 18:15:44

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:13:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e24873df-8a26-4643-b383-dd84ab832852'	System	28 Sep 2020 18:15:44
User entered 'No (N)'	System	28 Sep 2020 18:15:44

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:13:43', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e24873df-8a26-4643-b383-dd84ab832852'	System	28 Sep 2020 18:15:44
User entered 'Yes (Y)'	System	28 Sep 2020 18:15:44

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:15:06', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e24873df-8a26-4643-b383-dd84ab832852'	System	28 Sep 2020 18:15:44
User entered '10'	System	28 Sep 2020 18:15:44

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:15:37', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e24873df-8a26-4643-b383-dd84ab832852'	System	28 Sep 2020 18:15:44
User entered 'None (1)'	System	28 Sep 2020 18:15:44



**US3002329**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:15:39', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e24873df-8a26-4643-b383-dd84ab832852'	System	28 Sep 2020 18:15:44
User entered '28 Sep 2020 13:15'	System	28 Sep 2020 18:15:44

**US3002329**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 13:11'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 2'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:58:16', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5111bd49-5a9c-4972-a209-9810462b80b0'	System	29 Sep 2020 21:59:41
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 21:59:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:58:29', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5111bd49-5a9c-4972-a209-9810462b80b0' User entered 'No (N)'	System	29 Sep 2020 21:59:41
	System	29 Sep 2020 21:59:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:58:32', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5111bd49-5a9c-4972-a209-9810462b80b0' User entered 'Yes (Y)'	System	29 Sep 2020 21:59:41
	System	29 Sep 2020 21:59:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:58:58', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5111bd49-5a9c-4972-a209-9810462b80b0' User entered '10'	System	29 Sep 2020 21:59:41



US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:34', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5111bd49-5a9c-4972-a209-9810462b80b0'	System	29 Sep 2020 21:59:41
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 21:59:41

**US3002329**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:37', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5111bd49-5a9c-4972-a209-9810462b80b0' User entered '29 Sep 2020 16:59'	System	29 Sep 2020 21:59:41
	System	29 Sep 2020 21:59:41

**US3002329**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 3'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'dcc17fab-03ba-4fc1-b033-a0e245033d23'	System	30 Sep 2020 17:04:26
User entered 'None (1)'	System	30 Sep 2020 17:04:26

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:07', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'dcc17fab-03ba-4fc1-b033-a0e245033d23' User entered 'No (N)'	System	30 Sep 2020 17:04:26
	System	30 Sep 2020 17:04:26

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:13', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'dcc17fab-03ba-4fc1-b033-a0e245033d23' User entered 'Yes (Y)'	System	30 Sep 2020 17:04:26
	System	30 Sep 2020 17:04:26



US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:18', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'dcc17fab-03ba-4fc1-b033-a0e245033d23' User entered '5'	System	30 Sep 2020 17:04:26
	System	30 Sep 2020 17:04:26

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:21', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'dcc17fab-03ba-4fc1-b033-a0e245033d23'	System	30 Sep 2020 17:04:26
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 17:04:26

**US3002329**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:23', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'dcc17fab-03ba-4fc1-b033-a0e245033d23' User entered '30 Sep 2020 12:04'	System	30 Sep 2020 17:04:26
	System	30 Sep 2020 17:04:26

**US3002329**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 4'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:49', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '368ce02c-e21e-4b17-998f-26f915c6328a' User entered 'None (1)'	System	01 Oct 2020 17:40:02
	System	01 Oct 2020 17:40:02

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:51', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '368ce02c-e21e-4b17-998f-26f915c6328a' User entered 'No (N)'	System	01 Oct 2020 17:40:02
	System	01 Oct 2020 17:40:02



US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:53', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '368ce02c-e21e-4b17-998f-26f915c6328a' User entered 'No (N)'	System	01 Oct 2020 17:40:02
	System	01 Oct 2020 17:40:02

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:56', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '368ce02c-e21e-4b17-998f-26f915c6328a' User entered 'None (1)'	System	01 Oct 2020 17:40:02
	System	01 Oct 2020 17:40:02

**US3002329**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:39:58', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '368ce02c-e21e-4b17-998f-26f915c6328a' User entered '01 Oct 2020 12:39'	System	01 Oct 2020 17:40:02
	System	01 Oct 2020 17:40:02

**US3002329**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 5'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:44', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7bc486c3-5b16-4400-893a-16242f551090'	System	02 Oct 2020 17:02:32
User entered 'None (1)'	System	02 Oct 2020 17:02:32

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:46', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7bc486c3-5b16-4400-893a-16242f551090'	System	02 Oct 2020 17:02:32
User entered 'No (N)'	System	02 Oct 2020 17:02:32



US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:48', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7bc486c3-5b16-4400-893a-16242f551090'	System	02 Oct 2020 17:02:32
User entered 'No (N)'	System	02 Oct 2020 17:02:32

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:49', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7bc486c3-5b16-4400-893a-16242f551090'	System	02 Oct 2020 17:02:32
User entered 'None (1)'	System	02 Oct 2020 17:02:32

**US3002329**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:51', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7bc486c3-5b16-4400-893a-16242f551090' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 17:02:32
	System	02 Oct 2020 17:02:32

**US3002329**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 6'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:38', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '41f20472-319f-42c4-a308-6d52afec9f9a'	System	03 Oct 2020 17:32:47
User entered 'None (1)'	System	03 Oct 2020 17:32:47

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:40', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '41f20472-319f-42c4-a308-6d52afec9f9a'	System	03 Oct 2020 17:32:47
User entered 'No (N)'	System	03 Oct 2020 17:32:47



US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:41', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '41f20472-319f-42c4-a308-6d52afec9f9a'	System	03 Oct 2020 17:32:47
User entered 'No (N)'	System	03 Oct 2020 17:32:47

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:43', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '41f20472-319f-42c4-a308-6d52afec9f9a'	System	03 Oct 2020 17:32:47
User entered 'None (1)'	System	03 Oct 2020 17:32:47

**US3002329**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:44', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '41f20472-319f-42c4-a308-6d52afec9f9a' User entered '03 Oct 2020 12:32'	System	03 Oct 2020 17:32:47
	System	03 Oct 2020 17:32:47

**US3002329**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 7'	System	28 Sep 2020 14:37:41

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:14', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '1b5c5c3a-762f-40d8-9787-60391393cb5e'	System	04 Oct 2020 17:10:23
User entered 'None (1)'	System	04 Oct 2020 17:10:23

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:16', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '1b5c5c3a-762f-40d8-9787-60391393cb5e' User entered 'No (N)'	System	04 Oct 2020 17:10:23
	System	04 Oct 2020 17:10:23



US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:18', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '1b5c5c3a-762f-40d8-9787-60391393cb5e' User entered 'No (N)'	System	04 Oct 2020 17:10:23
	System	04 Oct 2020 17:10:23

US3002329

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:19', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '1b5c5c3a-762f-40d8-9787-60391393cb5e'	System	04 Oct 2020 17:10:23
User entered 'None (1)'	System	04 Oct 2020 17:10:23

**US3002329**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:21', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '1b5c5c3a-762f-40d8-9787-60391393cb5e' User entered '04 Oct 2020 12:10'	System	04 Oct 2020 17:10:23
	System	04 Oct 2020 17:10:23

**US3002329**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:57:56', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '21ad7967-a151-4547-9b47-a79377e6eae5' User entered 'None (0)'	System	28 Sep 2020 14:58:28
	System	28 Sep 2020 14:58:28

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:58:12', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '21ad7967-a151-4547-9b47-a79377e6eae5' User entered 'None (0)'	System	28 Sep 2020 14:58:28
	System	28 Sep 2020 14:58:28



**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:58:14', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '21ad7967-a151-4547-9b47-a79377e6eae5' User entered 'None (0)'	System	28 Sep 2020 14:58:28
	System	28 Sep 2020 14:58:28

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:58:15', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '21ad7967-a151-4547-9b47-a79377e6eae5' User entered 'None (0)'	System	28 Sep 2020 14:58:28
	System	28 Sep 2020 14:58:28

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:58:16', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '21ad7967-a151-4547-9b47-a79377e6eae5' User entered 'None (0)'	System	28 Sep 2020 14:58:28
	System	28 Sep 2020 14:58:28

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:58:18', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '21ad7967-a151-4547-9b47-a79377e6eae5' User entered 'None (0)'	System	28 Sep 2020 14:58:28
	System	28 Sep 2020 14:58:28

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:58:20', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '21ad7967-a151-4547-9b47-a79377e6eae5' User entered 'No (N)'	System	28 Sep 2020 14:58:28
	System	28 Sep 2020 14:58:28

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T09:58:25', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '21ad7967-a151-4547-9b47-a79377e6eae5' User entered '28 Sep 2020 09:58'	System	28 Sep 2020 14:58:28
	System	28 Sep 2020 14:58:28

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 09:46'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 12:16'	System	28 Sep 2020 14:37:41



US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:15:44', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f19e3c74-e83f-4e21-86d2-b8134af1989c' User entered 'None (0)'	System	28 Sep 2020 18:16:11
	System	28 Sep 2020 18:16:11

**US3002329**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:15:48', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f19e3c74-e83f-4e21-86d2-b8134af1989c' User entered 'None (0)'	System	28 Sep 2020 18:16:11
	System	28 Sep 2020 18:16:11

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:15:50', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f19e3c74-e83f-4e21-86d2-b8134af1989c' User entered 'None (0)'	System	28 Sep 2020 18:16:11
	System	28 Sep 2020 18:16:11

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:15:56', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f19e3c74-e83f-4e21-86d2-b8134af1989c' User entered 'None (0)'	System	28 Sep 2020 18:16:11
	System	28 Sep 2020 18:16:11

**US3002329**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:15:58', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f19e3c74-e83f-4e21-86d2-b8134af1989c' User entered 'None (0)'	System	28 Sep 2020 18:16:11
	System	28 Sep 2020 18:16:11

**US3002329**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:16:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f19e3c74-e83f-4e21-86d2-b8134af1989c' User entered 'None (0)'	System	28 Sep 2020 18:16:11
	System	28 Sep 2020 18:16:11

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:16:03', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f19e3c74-e83f-4e21-86d2-b8134af1989c' User entered 'No (N)'	System	28 Sep 2020 18:16:11
	System	28 Sep 2020 18:16:11



**US3002329**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-28T13:16:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f19e3c74-e83f-4e21-86d2-b8134af1989c' User entered '28 Sep 2020 13:16'	System	28 Sep 2020 18:16:11
	System	28 Sep 2020 18:16:11

**US3002329**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '28 Sep 2020 13:11'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 2'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:41', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '419f58e6-08e7-4caf-a44d-678b50e61f65' User entered 'None (0)'	System	29 Sep 2020 22:00:06
	System	29 Sep 2020 22:00:06

**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:44', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '419f58e6-08e7-4caf-a44d-678b50e61f65' User entered 'None (0)'	System	29 Sep 2020 22:00:06
	System	29 Sep 2020 22:00:06

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:48', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '419f58e6-08e7-4caf-a44d-678b50e61f65' User entered 'None (0)'	System	29 Sep 2020 22:00:06
	System	29 Sep 2020 22:00:06

**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:50', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '419f58e6-08e7-4caf-a44d-678b50e61f65' User entered 'None (0)'	System	29 Sep 2020 22:00:06
	System	29 Sep 2020 22:00:06



**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:52', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '419f58e6-08e7-4caf-a44d-678b50e61f65' User entered 'None (0)'	System	29 Sep 2020 22:00:06
	System	29 Sep 2020 22:00:06

**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:53', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '419f58e6-08e7-4caf-a44d-678b50e61f65' User entered 'None (0)'	System	29 Sep 2020 22:00:06
	System	29 Sep 2020 22:00:06

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:55', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '419f58e6-08e7-4caf-a44d-678b50e61f65'	System	29 Sep 2020 22:00:06
User entered 'No (N)'	System	29 Sep 2020 22:00:06

**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-29T16:59:57', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '419f58e6-08e7-4caf-a44d-678b50e61f65'	System	29 Sep 2020 22:00:06
User entered '29 Sep 2020 16:59'	System	29 Sep 2020 22:00:06

**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 3'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:27', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7c02d694-ae06-442a-9c73-f7943b72dd30' User entered 'None (0)'	System	30 Sep 2020 17:04:45
	System	30 Sep 2020 17:04:45



**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:28', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7c02d694-ae06-442a-9c73-f7943b72dd30' User entered 'None (0)'	System	30 Sep 2020 17:04:45
	System	30 Sep 2020 17:04:45

**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:30', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7c02d694-ae06-442a-9c73-f7943b72dd30' User entered 'None (0)'	System	30 Sep 2020 17:04:45
	System	30 Sep 2020 17:04:45

**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7c02d694-ae06-442a-9c73-f7943b72dd30' User entered 'None (0)'	System	30 Sep 2020 17:04:45
	System	30 Sep 2020 17:04:45

**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:34', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7c02d694-ae06-442a-9c73-f7943b72dd30' User entered 'None (0)'	System	30 Sep 2020 17:04:45
	System	30 Sep 2020 17:04:45

**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:35', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7c02d694-ae06-442a-9c73-f7943b72dd30' User entered 'None (0)'	System	30 Sep 2020 17:04:45
	System	30 Sep 2020 17:04:45

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:38', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7c02d694-ae06-442a-9c73-f7943b72dd30' User entered 'No (N)'	System	30 Sep 2020 17:04:45
	System	30 Sep 2020 17:04:45

**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-09-30T12:04:40', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '7c02d694-ae06-442a-9c73-f7943b72dd30' User entered '30 Sep 2020 12:04'	System	30 Sep 2020 17:04:45
	System	30 Sep 2020 17:04:45

**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:37:41



**US3002329**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 4'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:40:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '34d5a28f-731e-40be-b9e0-8c4bfd40ae16' User entered 'None (0)'	System	01 Oct 2020 17:40:14
	System	01 Oct 2020 17:40:14

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:40:02', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '34d5a28f-731e-40be-b9e0-8c4bfd40ae16' User entered 'None (0)'	System	01 Oct 2020 17:40:14
	System	01 Oct 2020 17:40:14

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:40:04', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '34d5a28f-731e-40be-b9e0-8c4bfd40ae16' User entered 'None (0)'	System	01 Oct 2020 17:40:14
	System	01 Oct 2020 17:40:14

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:40:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '34d5a28f-731e-40be-b9e0-8c4bfd40ae16' User entered 'None (0)'	System	01 Oct 2020 17:40:14
	System	01 Oct 2020 17:40:14

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:40:06', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '34d5a28f-731e-40be-b9e0-8c4bfd40ae16' User entered 'None (0)'	System	01 Oct 2020 17:40:14
	System	01 Oct 2020 17:40:14

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:40:07', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '34d5a28f-731e-40be-b9e0-8c4bfd40ae16' User entered 'None (0)'	System	01 Oct 2020 17:40:14
	System	01 Oct 2020 17:40:14



US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:40:09', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '34d5a28f-731e-40be-b9e0-8c4bfd40ae16'	System	01 Oct 2020 17:40:14
User entered 'No (N)'	System	01 Oct 2020 17:40:14

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-01T12:40:10', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '34d5a28f-731e-40be-b9e0-8c4bfd40ae16' User entered '01 Oct 2020 12:40'	System	01 Oct 2020 17:40:14
	System	01 Oct 2020 17:40:14

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 5'	System	28 Sep 2020 14:37:41

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:54', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f73482f8-52bb-46e8-b672-98217e6eb68b' User entered 'None (0)'	System	02 Oct 2020 17:02:46
	System	02 Oct 2020 17:02:46

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:56', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f73482f8-52bb-46e8-b672-98217e6eb68b' User entered 'None (0)'	System	02 Oct 2020 17:02:46
	System	02 Oct 2020 17:02:46

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:57', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f73482f8-52bb-46e8-b672-98217e6eb68b' User entered 'None (0)'	System	02 Oct 2020 17:02:46
	System	02 Oct 2020 17:02:46



**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:01:59', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f73482f8-52bb-46e8-b672-98217e6eb68b' User entered 'None (0)'	System	02 Oct 2020 17:02:46
	System	02 Oct 2020 17:02:46

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:02:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f73482f8-52bb-46e8-b672-98217e6eb68b' User entered 'None (0)'	System	02 Oct 2020 17:02:46
	System	02 Oct 2020 17:02:46

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:02:02', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f73482f8-52bb-46e8-b672-98217e6eb68b' User entered 'None (0)'	System	02 Oct 2020 17:02:46
	System	02 Oct 2020 17:02:46

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:02:04', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f73482f8-52bb-46e8-b672-98217e6eb68b' User entered 'No (N)'	System	02 Oct 2020 17:02:46
	System	02 Oct 2020 17:02:46

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-02T12:02:06', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f73482f8-52bb-46e8-b672-98217e6eb68b' User entered '02 Oct 2020 12:02'	System	02 Oct 2020 17:02:46
	System	02 Oct 2020 17:02:46

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 6'	System	28 Sep 2020 14:37:41



**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:47', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '577348e5-c2d1-436e-9e33-8285322ad5d9' User entered 'None (0)'	System	03 Oct 2020 17:33:06
	System	03 Oct 2020 17:33:06

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:49', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '577348e5-c2d1-436e-9e33-8285322ad5d9' User entered 'None (0)'	System	03 Oct 2020 17:33:06
	System	03 Oct 2020 17:33:06

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:50', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '577348e5-c2d1-436e-9e33-8285322ad5d9' User entered 'None (0)'	System	03 Oct 2020 17:33:06
	System	03 Oct 2020 17:33:06

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:51', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '577348e5-c2d1-436e-9e33-8285322ad5d9' User entered 'None (0)'	System	03 Oct 2020 17:33:06
	System	03 Oct 2020 17:33:06

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:52', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '577348e5-c2d1-436e-9e33-8285322ad5d9' User entered 'None (0)'	System	03 Oct 2020 17:33:06
	System	03 Oct 2020 17:33:06

**US3002329**

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

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

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:54', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '577348e5-c2d1-436e-9e33-8285322ad5d9' User entered 'None (0)'	System	03 Oct 2020 17:33:06
	System	03 Oct 2020 17:33:06

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:32:58', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '577348e5-c2d1-436e-9e33-8285322ad5d9' User entered 'No (N)'	System	03 Oct 2020 17:33:06
	System	03 Oct 2020 17:33:06

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-03T12:33:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '577348e5-c2d1-436e-9e33-8285322ad5d9' User entered '03 Oct 2020 12:33'	System	03 Oct 2020 17:33:06
	System	03 Oct 2020 17:33:06



**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	28 Sep 2020 14:37:41
User entered 'Day 7'	System	28 Sep 2020 14:37:41

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:24', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0b409e1-92e6-41ff-ab9a-5932f6f82b36'	System	04 Oct 2020 17:10:37
User entered 'None (0)'	System	04 Oct 2020 17:10:37

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:25', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0b409e1-92e6-41ff-ab9a-5932f6f82b36'	System	04 Oct 2020 17:10:37
User entered 'None (0)'	System	04 Oct 2020 17:10:37

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:26', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0b409e1-92e6-41ff-ab9a-5932f6f82b36'	System	04 Oct 2020 17:10:37
User entered 'None (0)'	System	04 Oct 2020 17:10:37

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:27', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0b409e1-92e6-41ff-ab9a-5932f6f82b36' User entered 'None (0)'	System	04 Oct 2020 17:10:37
	System	04 Oct 2020 17:10:37

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:29', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0b409e1-92e6-41ff-ab9a-5932f6f82b36'	System	04 Oct 2020 17:10:37
User entered 'None (0)'	System	04 Oct 2020 17:10:37



**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:30', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0b409e1-92e6-41ff-ab9a-5932f6f82b36' User entered 'None (0)'	System	04 Oct 2020 17:10:37
	System	04 Oct 2020 17:10:37

US3002329

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:32', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0b409e1-92e6-41ff-ab9a-5932f6f82b36'	System	04 Oct 2020 17:10:37
User entered 'No (N)'	System	04 Oct 2020 17:10:37

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-04T12:10:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0b409e1-92e6-41ff-ab9a-5932f6f82b36'	System	04 Oct 2020 17:10:37
User entered '04 Oct 2020 12:10'	System	04 Oct 2020 17:10:37

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:37:41

**US3002329**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:37:41

**US3002329**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:00:50

**US3002329**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:00:50

**US3002329**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:00:50



**US3002329**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:00:50

**US3002329**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:00:53

**US3002329**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'I'	System	21 Oct 2020 21:00:53

**US3002329**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:09

**US3002329**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:09

**US3002329**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:09

**US3002329**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:09

**US3002329**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:12



**US3002329**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'I'	System	21 Oct 2020 21:01:12

**US3002329**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:24

**US3002329**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:24

**US3002329**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:24

**US3002329**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:24

**US3002329**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 21:01:27

**US3002329**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'I'	System	21 Oct 2020 21:01:27

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:52:47



**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:52:47

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:52:47

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'VISIT2'	System	30 Oct 2020 15:52:47

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Oct 2020 15:53:37

US3002329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:09'	(b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '30 Oct 2020 08:09'	System	30 Oct 2020 15:53:37



US3002329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '72'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'bpm'	System	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

US3002329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'breaths/min'	System	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '122'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37



**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '75'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

US3002329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:52:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

US3002329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '09:57'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '30 Oct 2020 09:57'	System	30 Oct 2020 15:53:37



**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '69'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'bpm'	System	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '12'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'breaths/min'	System	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '113'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37



**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '82'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:37

US3002329

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:52:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	30 Oct 2020 15:53:37

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:52:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:51

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:52:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:53:51

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:00

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:00

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:00



**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:00

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:00

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:00

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:00

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered empty.	System	30 Oct 2020 15:54:00

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:52:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	30 Oct 2020 14:56:04

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:52:37**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	30 Oct 2020 14:56:04

US3002329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	Tiffany Nemecek (b) (4)	30 Oct 2020 14:56:04



**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:52:37**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'MRNA-1273 OR PLACEBO'	System	30 Oct 2020 14:56:04

US3002329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '30 Oct 2020'	Tiffany Nemecek (b) (4)	30 Oct 2020 14:56:04

US3002329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '09:27'	(b) (4) Tiffany Nemecek (b) (4)	30 Oct 2020 14:56:04

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:52:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '30 Oct 2020 09:27'	System	30 Oct 2020 14:56:04

US3002329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Left Arm (LEFT ARM)'	Tiffany Nemecek (b) (4)	30 Oct 2020 14:56:04

US3002329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'ONCE'	System	30 Oct 2020 14:56:04

US3002329

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:52:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'INTRAMUSCULAR'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:15



US3002329

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:52:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:15

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:47'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:15

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '30 Oct 2020 08:47'	System	30 Oct 2020 15:54:15

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:52:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:26

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Oct 2020 15:54:26

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:26

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:23'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:26

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '30 Oct 2020 08:23'	System	30 Oct 2020 15:54:26



**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Oct 2020 15:54:26

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:26

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:26

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered empty.	System	30 Oct 2020 15:54:26

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:54:29

**US3002329**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '1'	System	30 Oct 2020 15:54:29

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fcd478e6-c614-416f-be62-7b30218ea558'	System	30 Oct 2020 14:59:15
User entered 'Yes (Y)'	System	30 Oct 2020 14:59:15



US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fcd478e6-c614-416f-be62-7b30218ea558' User entered '98.2'	System	30 Oct 2020 14:59:15
	System	30 Oct 2020 14:59:15

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:08', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fcd478e6-c614-416f-be62-7b30218ea558'	System	30 Oct 2020 14:59:15
User entered 'No (N)'	System	30 Oct 2020 14:59:15

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:11', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fcd478e6-c614-416f-be62-7b30218ea558' User entered '30 Oct 2020 09:59'	System	30 Oct 2020 14:59:15
	System	30 Oct 2020 14:59:15

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 09:47'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 12:17'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:58:28', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '78c34c41-7dc8-41a4-a775-669e51b4608c' User entered 'Yes (Y)'	System	30 Oct 2020 18:58:42
	System	30 Oct 2020 18:58:42

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:58:34', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '78c34c41-7dc8-41a4-a775-669e51b4608c' User entered '98.7'	System	30 Oct 2020 18:58:42
	System	30 Oct 2020 18:58:42



US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:58:36', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '78c34c41-7dc8-41a4-a775-669e51b4608c' User entered 'No (N)'	System	30 Oct 2020 18:58:42
	System	30 Oct 2020 18:58:42

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:58:39', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '78c34c41-7dc8-41a4-a775-669e51b4608c' User entered '30 Oct 2020 13:58'	System	30 Oct 2020 18:58:42
	System	30 Oct 2020 18:58:42

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 13:12'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 2'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:27', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cfb2657f-d73d-40a3-95fd-90f41e29d5a2'	System	01 Nov 2020 16:04:50
User entered 'Yes (Y)'	System	01 Nov 2020 16:04:50

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:31', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cfb2657f-d73d-40a3-95fd-90f41e29d5a2' User entered '98.7'	System	01 Nov 2020 16:04:50
	System	01 Nov 2020 16:04:50

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:35', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cfb2657f-d73d-40a3-95fd-90f41e29d5a2'	System	01 Nov 2020 16:04:50
User entered 'Yes (Y)'	System	01 Nov 2020 16:04:50



US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'done' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 05:38:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:43', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cfb2657f-d73d-40a3-95fd-90f41e29d5a2' User entered '1'	Kimberly Mueller (b) (4) (b) (4)	18 Nov 2020 23:10:54
	System	01 Nov 2020 16:04:50
	System	01 Nov 2020 16:04:50
	System	01 Nov 2020 16:04:50

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:52:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:43', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cfb2657f-d73d-40a3-95fd-90f41e29d5a2'	System	01 Nov 2020 16:04:50
User entered '0'	System	01 Nov 2020 16:04:50

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:46', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cfb2657f-d73d-40a3-95fd-90f41e29d5a2'	System	01 Nov 2020 16:04:50
User entered '01 Nov 2020 10:04'	System	01 Nov 2020 16:04:50

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 3'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:15', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63641b1b-7630-4b8b-a9cb-0c298efa8b50'	System	02 Nov 2020 15:35:28
User entered 'Yes (Y)'	System	02 Nov 2020 15:35:28

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:20', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63641b1b-7630-4b8b-a9cb-0c298efa8b50' User entered '98.0'	System	02 Nov 2020 15:35:28
	System	02 Nov 2020 15:35:28



US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:22', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63641b1b-7630-4b8b-a9cb-0c298efa8b50'	System	02 Nov 2020 15:35:28
User entered 'No (N)'	System	02 Nov 2020 15:35:28

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:25', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63641b1b-7630-4b8b-a9cb-0c298efa8b50' User entered '02 Nov 2020 09:35'	System	02 Nov 2020 15:35:28
	System	02 Nov 2020 15:35:28

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 4'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:00:34', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '0f555d62-90db-4187-92be-884a0123b56c'	System	02 Nov 2020 18:09:56
User entered 'Yes (Y)'	System	02 Nov 2020 18:09:56

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:00:49', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '0f555d62-90db-4187-92be-884a0123b56c' User entered '98.0'	System	02 Nov 2020 18:09:56
	System	02 Nov 2020 18:09:56

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:09:52', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '0f555d62-90db-4187-92be-884a0123b56c'	System	02 Nov 2020 18:09:56
User entered 'No (N)'	System	02 Nov 2020 18:09:56



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:09:55', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '0f555d62-90db-4187-92be-884a0123b56c'	System	02 Nov 2020 18:09:56
User entered '02 Nov 2020 12:09'	System	02 Nov 2020 18:09:56

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 5'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:41', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c9d0f4e8-a583-4691-872d-4a14d4419dff' User entered 'Yes (Y)'	System	04 Nov 2020 14:33:52
	System	04 Nov 2020 14:33:52

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:45', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c9d0f4e8-a583-4691-872d-4a14d4419dff' User entered '98.0'	System	04 Nov 2020 14:33:52
	System	04 Nov 2020 14:33:52

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:47', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c9d0f4e8-a583-4691-872d-4a14d4419dff'	System	04 Nov 2020 14:33:52
User entered 'No (N)'	System	04 Nov 2020 14:33:52

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:50', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c9d0f4e8-a583-4691-872d-4a14d4419dff' User entered '04 Nov 2020 08:33'	System	04 Nov 2020 14:33:52
	System	04 Nov 2020 14:33:52



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 6'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:00:48', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '083c9c3e-7083-492a-be17-57c0d7b2b583' User entered 'Yes (Y)'	System	04 Nov 2020 18:01:03
	System	04 Nov 2020 18:01:03

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:00:51', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '083c9c3e-7083-492a-be17-57c0d7b2b583' User entered '98.0'	System	04 Nov 2020 18:01:03
	System	04 Nov 2020 18:01:03

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:00:53', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '083c9c3e-7083-492a-be17-57c0d7b2b583'	System	04 Nov 2020 18:01:03
User entered 'No (N)'	System	04 Nov 2020 18:01:03

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:00:57', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '083c9c3e-7083-492a-be17-57c0d7b2b583' User entered '04 Nov 2020 12:00'	System	04 Nov 2020 18:01:03
	System	04 Nov 2020 18:01:03

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:56:04



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 7'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:51:53', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'd445b846-e627-4016-951a-0af88d9f94d9'	System	05 Nov 2020 22:52:07
User entered 'Yes (Y)'	System	05 Nov 2020 22:52:07

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'd445b846-e627-4016-951a-0af88d9f94d9' User entered '98.0'	System	05 Nov 2020 22:52:07
	System	05 Nov 2020 22:52:07

US3002329

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:02', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'd445b846-e627-4016-951a-0af88d9f94d9'	System	05 Nov 2020 22:52:07
User entered 'No (N)'	System	05 Nov 2020 22:52:07

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'd445b846-e627-4016-951a-0af88d9f94d9' User entered '05 Nov 2020 16:52'	System	05 Nov 2020 22:52:07
	System	05 Nov 2020 22:52:07

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:56:04



US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:17', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '556dd56b-b51b-4259-a773-ba2147d77d06'	System	30 Oct 2020 14:59:30
User entered 'None (1)'	System	30 Oct 2020 14:59:30

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:21', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '556dd56b-b51b-4259-a773-ba2147d77d06'	System	30 Oct 2020 14:59:30
User entered 'No (N)'	System	30 Oct 2020 14:59:30

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:22', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '556dd56b-b51b-4259-a773-ba2147d77d06'	System	30 Oct 2020 14:59:30
User entered 'No (N)'	System	30 Oct 2020 14:59:30

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:25', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '556dd56b-b51b-4259-a773-ba2147d77d06'	System	30 Oct 2020 14:59:30
User entered 'None (1)'	System	30 Oct 2020 14:59:30

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:28', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '556dd56b-b51b-4259-a773-ba2147d77d06'	System	30 Oct 2020 14:59:30
User entered '30 Oct 2020 09:59'	System	30 Oct 2020 14:59:30

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 09:47'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 12:17'	System	30 Oct 2020 14:56:04



US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:58:46', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e07904d7-eb94-48eb-961c-e5c484fc4baa'	System	30 Oct 2020 19:00:10
User entered 'Does not interfere with activity (2)'	System	30 Oct 2020 19:00:10

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:59:29', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e07904d7-eb94-48eb-961c-e5c484fc4baa'	System	30 Oct 2020 19:00:10
User entered 'No (N)'	System	30 Oct 2020 19:00:10

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:59:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e07904d7-eb94-48eb-961c-e5c484fc4baa'	System	30 Oct 2020 19:00:10
User entered 'Yes (Y)'	System	30 Oct 2020 19:00:10

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

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)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:59:39', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e07904d7-eb94-48eb-961c-e5c484fc4baa'	System	30 Oct 2020 19:00:10
User entered '1'	System	30 Oct 2020 19:00:10

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T13:59:58', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e07904d7-eb94-48eb-961c-e5c484fc4baa'	System	30 Oct 2020 19:00:10
User entered 'None (1)'	System	30 Oct 2020 19:00:10

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'e07904d7-eb94-48eb-961c-e5c484fc4baa'	System	30 Oct 2020 19:00:10
User entered '30 Oct 2020 14:00'	System	30 Oct 2020 19:00:10

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 13:12'	System	30 Oct 2020 14:56:04



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 2'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:53', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '699c212b-9e13-4281-b8ed-c580711ae055'	System	01 Nov 2020 16:05:15
User entered 'Does not interfere with activity (2)'	System	01 Nov 2020 16:05:15

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:56', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '699c212b-9e13-4281-b8ed-c580711ae055'	System	01 Nov 2020 16:05:15
User entered 'Yes (Y)'	System	01 Nov 2020 16:05:15

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:04:59', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '699c212b-9e13-4281-b8ed-c580711ae055' User entered '5'	System	01 Nov 2020 16:05:15
	System	01 Nov 2020 16:05:15

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '699c212b-9e13-4281-b8ed-c580711ae055'	System	01 Nov 2020 16:05:15
User entered 'Yes (Y)'	System	01 Nov 2020 16:05:15

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

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)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '699c212b-9e13-4281-b8ed-c580711ae055' User entered '5'	System	01 Nov 2020 16:05:15
	System	01 Nov 2020 16:05:15

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:09', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '699c212b-9e13-4281-b8ed-c580711ae055'	System	01 Nov 2020 16:05:15
User entered 'None (1)'	System	01 Nov 2020 16:05:15



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:12', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '699c212b-9e13-4281-b8ed-c580711ae055' User entered '01 Nov 2020 10:05'	System	01 Nov 2020 16:05:15
	System	01 Nov 2020 16:05:15

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 3'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:31', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c635ab54-f545-4ef9-b7d1-8062f9fd2a35'	System	02 Nov 2020 15:35:42
User entered 'None (1)'	System	02 Nov 2020 15:35:42

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c635ab54-f545-4ef9-b7d1-8062f9fd2a35'	System	02 Nov 2020 15:35:42
User entered 'No (N)'	System	02 Nov 2020 15:35:42

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:35', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c635ab54-f545-4ef9-b7d1-8062f9fd2a35'	System	02 Nov 2020 15:35:42
User entered 'No (N)'	System	02 Nov 2020 15:35:42

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:37', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c635ab54-f545-4ef9-b7d1-8062f9fd2a35'	System	02 Nov 2020 15:35:42
User entered 'None (1)'	System	02 Nov 2020 15:35:42



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:39', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c635ab54-f545-4ef9-b7d1-8062f9fd2a35'	System	02 Nov 2020 15:35:42
User entered '02 Nov 2020 09:35'	System	02 Nov 2020 15:35:42

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 4'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:09:59', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b94fd13b-c964-42f3-a817-ba05c1d63b44'	System	02 Nov 2020 18:10:08
User entered 'None (1)'	System	02 Nov 2020 18:10:08

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b94fd13b-c964-42f3-a817-ba05c1d63b44'	System	02 Nov 2020 18:10:08
User entered 'No (N)'	System	02 Nov 2020 18:10:08

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:02', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b94fd13b-c964-42f3-a817-ba05c1d63b44'	System	02 Nov 2020 18:10:08
User entered 'No (N)'	System	02 Nov 2020 18:10:08

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:03', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b94fd13b-c964-42f3-a817-ba05c1d63b44'	System	02 Nov 2020 18:10:08
User entered 'None (1)'	System	02 Nov 2020 18:10:08



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'b94fd13b-c964-42f3-a817-ba05c1d63b44'	System	02 Nov 2020 18:10:08
User entered '02 Nov 2020 12:10'	System	02 Nov 2020 18:10:08

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 5'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:52', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2c80df0e-caac-427e-912a-daa79c1d1560'	System	04 Nov 2020 14:34:03
User entered 'None (1)'	System	04 Nov 2020 14:34:03

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:54', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2c80df0e-caac-427e-912a-daa79c1d1560'	System	04 Nov 2020 14:34:03
User entered 'No (N)'	System	04 Nov 2020 14:34:03

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:55', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2c80df0e-caac-427e-912a-daa79c1d1560'	System	04 Nov 2020 14:34:03
User entered 'No (N)'	System	04 Nov 2020 14:34:03

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:57', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2c80df0e-caac-427e-912a-daa79c1d1560'	System	04 Nov 2020 14:34:03
User entered 'None (1)'	System	04 Nov 2020 14:34:03



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:33:59', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2c80df0e-caac-427e-912a-daa79c1d1560' User entered '04 Nov 2020 08:33'	System	04 Nov 2020 14:34:03
	System	04 Nov 2020 14:34:03

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 6'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2ddbe118-826f-4b20-bc18-5beafedbf1a8'	System	04 Nov 2020 18:01:14
User entered 'None (1)'	System	04 Nov 2020 18:01:14

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2ddbe118-826f-4b20-bc18-5beafedbf1a8' User entered 'No (N)'	System	04 Nov 2020 18:01:14
	System	04 Nov 2020 18:01:14

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:02', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2ddbe118-826f-4b20-bc18-5beafedbf1a8' User entered 'No (N)'	System	04 Nov 2020 18:01:14
	System	04 Nov 2020 18:01:14

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:52:37

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:03', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2ddbe118-826f-4b20-bc18-5beafedbf1a8' User entered 'None (1)'	System	04 Nov 2020 18:01:14
	System	04 Nov 2020 18:01:14



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:06', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '2ddbe118-826f-4b20-bc18-5beafedbf1a8' User entered '04 Nov 2020 12:01'	System	04 Nov 2020 18:01:14
	System	04 Nov 2020 18:01:14

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 7'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:08', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cdc9123c-41d4-4532-8661-aa8a344c9869' User entered 'None (1)'	System	05 Nov 2020 22:52:18
	System	05 Nov 2020 22:52:18

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:10', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cdc9123c-41d4-4532-8661-aa8a344c9869' User entered 'No (N)'	System	05 Nov 2020 22:52:18
	System	05 Nov 2020 22:52:18

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:11', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cdc9123c-41d4-4532-8661-aa8a344c9869' User entered 'No (N)'	System	05 Nov 2020 22:52:18
	System	05 Nov 2020 22:52:18

US3002329

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:52:37

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:13', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cdc9123c-41d4-4532-8661-aa8a344c9869' User entered 'None (1)'	System	05 Nov 2020 22:52:18
	System	05 Nov 2020 22:52:18



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:15', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cdc9123c-41d4-4532-8661-aa8a344c9869' User entered '05 Nov 2020 16:52'	System	05 Nov 2020 22:52:18
	System	05 Nov 2020 22:52:18

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:31', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63220d55-56af-4a9c-a075-d328fd32b4cd' User entered 'None (0)'	System	30 Oct 2020 14:59:53
	System	30 Oct 2020 14:59:53

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63220d55-56af-4a9c-a075-d328fd32b4cd' User entered 'None (0)'	System	30 Oct 2020 14:59:53
	System	30 Oct 2020 14:59:53

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:35', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63220d55-56af-4a9c-a075-d328fd32b4cd' User entered 'None (0)'	System	30 Oct 2020 14:59:53
	System	30 Oct 2020 14:59:53

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:36', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63220d55-56af-4a9c-a075-d328fd32b4cd' User entered 'None (0)'	System	30 Oct 2020 14:59:53
	System	30 Oct 2020 14:59:53



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:38', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63220d55-56af-4a9c-a075-d328fd32b4cd' User entered 'None (0)'	System	30 Oct 2020 14:59:53
	System	30 Oct 2020 14:59:53

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:39', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63220d55-56af-4a9c-a075-d328fd32b4cd' User entered 'None (0)'	System	30 Oct 2020 14:59:53
	System	30 Oct 2020 14:59:53

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:52:37

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:43', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63220d55-56af-4a9c-a075-d328fd32b4cd' User entered 'No (N)'	System	30 Oct 2020 14:59:53
	System	30 Oct 2020 14:59:53

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T09:59:46', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '63220d55-56af-4a9c-a075-d328fd32b4cd' User entered '30 Oct 2020 09:59'	System	30 Oct 2020 14:59:53
	System	30 Oct 2020 14:59:53

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 09:47'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 12:17'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 1, after vaccination (at home)'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5185e6aa-93f9-44de-bc00-74e9ad688e4d'	System	30 Oct 2020 19:00:21
User entered 'No interference with activity (1)'	System	30 Oct 2020 19:00:21



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:07', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5185e6aa-93f9-44de-bc00-74e9ad688e4d' User entered 'None (0)'	System	30 Oct 2020 19:00:21
	System	30 Oct 2020 19:00:21

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:08', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5185e6aa-93f9-44de-bc00-74e9ad688e4d' User entered 'None (0)'	System	30 Oct 2020 19:00:21
	System	30 Oct 2020 19:00:21

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:09', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5185e6aa-93f9-44de-bc00-74e9ad688e4d' User entered 'None (0)'	System	30 Oct 2020 19:00:21
	System	30 Oct 2020 19:00:21

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:11', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5185e6aa-93f9-44de-bc00-74e9ad688e4d' User entered 'None (0)'	System	30 Oct 2020 19:00:21
	System	30 Oct 2020 19:00:21

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:13', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5185e6aa-93f9-44de-bc00-74e9ad688e4d' User entered 'None (0)'	System	30 Oct 2020 19:00:21
	System	30 Oct 2020 19:00:21

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:52:37

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:15', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5185e6aa-93f9-44de-bc00-74e9ad688e4d' User entered 'No (N)'	System	30 Oct 2020 19:00:21
	System	30 Oct 2020 19:00:21

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-10-30T14:00:17', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5185e6aa-93f9-44de-bc00-74e9ad688e4d' User entered '30 Oct 2020 14:00'	System	30 Oct 2020 19:00:21
	System	30 Oct 2020 19:00:21

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '30 Oct 2020 13:12'	System	30 Oct 2020 14:56:04



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 2'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:17', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6c8b12f7-44dd-42e0-ae44-d6635f69188d' User entered 'None (0)'	System	01 Nov 2020 16:05:39
	System	01 Nov 2020 16:05:39

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:20', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6c8b12f7-44dd-42e0-ae44-d6635f69188d' User entered 'No interference with activity (1)'	System	01 Nov 2020 16:05:39
	System	01 Nov 2020 16:05:39

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:23', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6c8b12f7-44dd-42e0-ae44-d6635f69188d' User entered 'No interference with activity (1)'	System	01 Nov 2020 16:05:39
	System	01 Nov 2020 16:05:39

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:25', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6c8b12f7-44dd-42e0-ae44-d6635f69188d' User entered 'No interference with activity (1)'	System	01 Nov 2020 16:05:39
	System	01 Nov 2020 16:05:39

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:26', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6c8b12f7-44dd-42e0-ae44-d6635f69188d' User entered 'None (0)'	System	01 Nov 2020 16:05:39
	System	01 Nov 2020 16:05:39

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:28', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6c8b12f7-44dd-42e0-ae44-d6635f69188d' User entered 'None (0)'	System	01 Nov 2020 16:05:39
	System	01 Nov 2020 16:05:39



US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:52:37

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:30', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6c8b12f7-44dd-42e0-ae44-d6635f69188d' User entered 'No (N)'	System	01 Nov 2020 16:05:39
	System	01 Nov 2020 16:05:39

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-01T10:05:32', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6c8b12f7-44dd-42e0-ae44-d6635f69188d' User entered '01 Nov 2020 10:05'	System	01 Nov 2020 16:05:39
	System	01 Nov 2020 16:05:39

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '31 Oct 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 3'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:43', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '37958349-45d7-4faf-8496-b1a23446f1d0'	System	02 Nov 2020 15:35:57
User entered 'No interference with activity (1)'	System	02 Nov 2020 15:35:57

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:45', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '37958349-45d7-4faf-8496-b1a23446f1d0' User entered 'None (0)'	System	02 Nov 2020 15:35:57
	System	02 Nov 2020 15:35:57

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:46', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '37958349-45d7-4faf-8496-b1a23446f1d0' User entered 'None (0)'	System	02 Nov 2020 15:35:57
	System	02 Nov 2020 15:35:57



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:48', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '37958349-45d7-4faf-8496-b1a23446f1d0' User entered 'None (0)'	System	02 Nov 2020 15:35:57
	System	02 Nov 2020 15:35:57

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:49', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '37958349-45d7-4faf-8496-b1a23446f1d0' User entered 'None (0)'	System	02 Nov 2020 15:35:57
	System	02 Nov 2020 15:35:57

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:50', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '37958349-45d7-4faf-8496-b1a23446f1d0' User entered 'None (0)'	System	02 Nov 2020 15:35:57
	System	02 Nov 2020 15:35:57

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:52:37

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:53', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '37958349-45d7-4faf-8496-b1a23446f1d0'	System	02 Nov 2020 15:35:57
User entered 'No (N)'	System	02 Nov 2020 15:35:57

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T09:35:55', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '37958349-45d7-4faf-8496-b1a23446f1d0' User entered '02 Nov 2020 09:35'	System	02 Nov 2020 15:35:57
	System	02 Nov 2020 15:35:57

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '01 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 4'	System	30 Oct 2020 14:56:04



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:08', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '45bf2271-b56e-48d3-ae79-0986d9da3f12' User entered 'None (0)'	System	02 Nov 2020 18:10:21
	System	02 Nov 2020 18:10:21

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:09', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '45bf2271-b56e-48d3-ae79-0986d9da3f12' User entered 'None (0)'	System	02 Nov 2020 18:10:21
	System	02 Nov 2020 18:10:21

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:10', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '45bf2271-b56e-48d3-ae79-0986d9da3f12' User entered 'None (0)'	System	02 Nov 2020 18:10:21
	System	02 Nov 2020 18:10:21

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:12', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '45bf2271-b56e-48d3-ae79-0986d9da3f12' User entered 'None (0)'	System	02 Nov 2020 18:10:21
	System	02 Nov 2020 18:10:21

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:13', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '45bf2271-b56e-48d3-ae79-0986d9da3f12' User entered 'None (0)'	System	02 Nov 2020 18:10:21
	System	02 Nov 2020 18:10:21

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:14', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '45bf2271-b56e-48d3-ae79-0986d9da3f12' User entered 'None (0)'	System	02 Nov 2020 18:10:21
	System	02 Nov 2020 18:10:21

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:52:37

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:15', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '45bf2271-b56e-48d3-ae79-0986d9da3f12' User entered 'No (N)'	System	02 Nov 2020 18:10:21
	System	02 Nov 2020 18:10:21

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-02T12:10:18', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '45bf2271-b56e-48d3-ae79-0986d9da3f12'	System	02 Nov 2020 18:10:21
User entered '02 Nov 2020 12:10'	System	02 Nov 2020 18:10:21



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '02 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 5'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:34:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '39dea9aa-d757-40d0-aedc-7433ea5e91a9' User entered 'None (0)'	System	04 Nov 2020 14:34:15
	System	04 Nov 2020 14:34:15

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:34:04', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '39dea9aa-d757-40d0-aedc-7433ea5e91a9' User entered 'None (0)'	System	04 Nov 2020 14:34:15
	System	04 Nov 2020 14:34:15

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:34:05', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '39dea9aa-d757-40d0-aedc-7433ea5e91a9' User entered 'None (0)'	System	04 Nov 2020 14:34:15
	System	04 Nov 2020 14:34:15

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:34:06', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '39dea9aa-d757-40d0-aedc-7433ea5e91a9' User entered 'None (0)'	System	04 Nov 2020 14:34:15
	System	04 Nov 2020 14:34:15

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:34:08', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '39dea9aa-d757-40d0-aedc-7433ea5e91a9' User entered 'None (0)'	System	04 Nov 2020 14:34:15
	System	04 Nov 2020 14:34:15



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:34:09', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '39dea9aa-d757-40d0-aedc-7433ea5e91a9' User entered 'None (0)'	System	04 Nov 2020 14:34:15
	System	04 Nov 2020 14:34:15

US3002329

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:52:37

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:34:11', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '39dea9aa-d757-40d0-aedc-7433ea5e91a9' User entered 'No (N)'	System	04 Nov 2020 14:34:15
	System	04 Nov 2020 14:34:15

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T08:34:13', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '39dea9aa-d757-40d0-aedc-7433ea5e91a9' User entered '04 Nov 2020 08:34'	System	04 Nov 2020 14:34:15
	System	04 Nov 2020 14:34:15

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '03 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 6'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:09', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '820ce2f0-d27e-4067-af75-6b37b4f050a5' User entered 'None (0)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:10', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '820ce2f0-d27e-4067-af75-6b37b4f050a5' User entered 'None (0)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:12', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '820ce2f0-d27e-4067-af75-6b37b4f050a5' User entered 'None (0)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:13', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '820ce2f0-d27e-4067-af75-6b37b4f050a5' User entered 'None (0)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:14', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '820ce2f0-d27e-4067-af75-6b37b4f050a5' User entered 'None (0)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:15', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '820ce2f0-d27e-4067-af75-6b37b4f050a5' User entered 'None (0)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:16', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '820ce2f0-d27e-4067-af75-6b37b4f050a5' User entered 'No (N)'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-04T12:01:18', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '820ce2f0-d27e-4067-af75-6b37b4f050a5' User entered '04 Nov 2020 12:01'	System	04 Nov 2020 18:01:23
	System	04 Nov 2020 18:01:23

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '04 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Nov 2020 11:59'	System	30 Oct 2020 14:56:04



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
Data entry locked.	System	30 Oct 2020 14:56:04
User entered 'Day 7'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:18', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '4a7757db-d7fa-44cb-aafa-45c11799036b' User entered 'None (0)'	System	05 Nov 2020 22:52:31
	System	05 Nov 2020 22:52:31

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:19', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '4a7757db-d7fa-44cb-aafa-45c11799036b' User entered 'None (0)'	System	05 Nov 2020 22:52:31
	System	05 Nov 2020 22:52:31

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:21', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '4a7757db-d7fa-44cb-aafa-45c11799036b' User entered 'None (0)'	System	05 Nov 2020 22:52:31
	System	05 Nov 2020 22:52:31

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:22', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '4a7757db-d7fa-44cb-aafa-45c11799036b' User entered 'None (0)'	System	05 Nov 2020 22:52:31
	System	05 Nov 2020 22:52:31

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:24', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '4a7757db-d7fa-44cb-aafa-45c11799036b' User entered 'None (0)'	System	05 Nov 2020 22:52:31
	System	05 Nov 2020 22:52:31

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:25', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '4a7757db-d7fa-44cb-aafa-45c11799036b' User entered 'None (0)'	System	05 Nov 2020 22:52:31
	System	05 Nov 2020 22:52:31

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:26', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '4a7757db-d7fa-44cb-aafa-45c11799036b' User entered 'No (N)'	System	05 Nov 2020 22:52:31
	System	05 Nov 2020 22:52:31



**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-05T16:52:28', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '4a7757db-d7fa-44cb-aafa-45c11799036b' User entered '05 Nov 2020 16:52'	System	05 Nov 2020 22:52:31
	System	05 Nov 2020 22:52:31

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '05 Nov 2020 12:00'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:52:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 22:15:26
User entered '06 Nov 2020 11:59'	System	30 Oct 2020 14:56:04

**US3002329**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:06

**US3002329**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:06

**US3002329**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:06

**US3002329**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 17:34:06

**US3002329**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:03:28



**US3002329**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'I'	System	25 Nov 2020 16:03:28

**US3002329**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:48:29
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	28 Mar 2021 22:28:50

**US3002329**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:48:29
User entered '13 Nov 2020'	(b) (4) Tiffany Nemecek (b) (4)	28 Mar 2021 22:28:50

US3002329

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:48:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tiffany Nemecek (b) (4)	28 Mar 2021 22:28:50

**US3002329**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:48:29
User entered empty.	(b) (4) Tiffany Nemecek (b) (4)	28 Mar 2021 22:28:50

**US3002329**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:03:34

**US3002329**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'I'	System	25 Nov 2020 16:03:34

US3002329

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:52:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	25 Nov 2020 16:03:50
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Nov 2020 16:03:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 16:03:46



**US3002329**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:03:46

**US3002329**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	25 Nov 2020 16:03:50
reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 16:03:50
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 16:03:46

**US3002329**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:03:46

**US3002329**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:03:54

**US3002329**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'I'	System	25 Nov 2020 16:03:54

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:56:49

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:56:49

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:56:49



**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'VISIT3'	System	11 Dec 2020 19:56:49

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '10:09'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '03 Dec 2020 10:09'	System	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05



**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '74'	(b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'bpm'	System	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '12'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'breaths/min'	System	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '116'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '80'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:05

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered 'mmHg'	System	11 Dec 2020 19:57:05



**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:52:37**

**Weight (derived)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:52:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:11

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:52:37**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:11

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:19

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:19

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '10:27'	(b) (4), (b) (6)	11 Dec 2020 19:57:19

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '03 Dec 2020 10:27'	System	11 Dec 2020 19:57:19



**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:57:23

**US3002329**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:38
User entered '1'	System	11 Dec 2020 19:57:23

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-28T08:16:39', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'bd553ae4-b3bb-468f-ad8c-80b8afae889b'	System	28 Nov 2020 14:16:46
User entered 'No (N)'	System	28 Nov 2020 14:16:46

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-28T08:16:41', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'bd553ae4-b3bb-468f-ad8c-80b8afae889b'	System	28 Nov 2020 14:16:46
User entered 'No (N)'	System	28 Nov 2020 14:16:46

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-11-28T08:16:44', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'bd553ae4-b3bb-468f-ad8c-80b8afae889b' User entered '28 Nov 2020 08:16:44'	System	28 Nov 2020 14:16:46
	System	28 Nov 2020 14:16:46

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-02T00:01:28', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'baa9ac28-633a-41bc-8403-d279ec8eeaf6'	System	02 Dec 2020 06:01:39
User entered 'No (N)'	System	02 Dec 2020 06:01:39

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-02T00:01:30', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'baa9ac28-633a-41bc-8403-d279ec8eeaf6'	System	02 Dec 2020 06:01:39
User entered 'No (N)'	System	02 Dec 2020 06:01:39

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-02T00:01:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'baa9ac28-633a-41bc-8403-d279ec8eeaf6' User entered '02 Dec 2020 00:01:33'	System	02 Dec 2020 06:01:39
	System	02 Dec 2020 06:01:39

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-09T00:01:15', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f8078dc6-037f-4b1c-9b11-e074d6013fda' User entered 'No (N)'	System	09 Dec 2020 06:01:36
	System	09 Dec 2020 06:01:36



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-09T00:01:22', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f8078dc6-037f-4b1c-9b11-e074d6013fda' User entered 'No (N)'	System	09 Dec 2020 06:01:36
	System	09 Dec 2020 06:01:36

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-09T00:01:24', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f8078dc6-037f-4b1c-9b11-e074d6013fda' User entered '09 Dec 2020 00:01:24'	System	09 Dec 2020 06:01:36
	System	09 Dec 2020 06:01:36

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-18T13:00:33', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '26ea295e-a2c8-404f-a145-a3fa628773f2'	System	18 Dec 2020 19:02:39
User entered 'No (N)'	System	18 Dec 2020 19:02:39

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-18T13:02:32', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '26ea295e-a2c8-404f-a145-a3fa628773f2'	System	18 Dec 2020 19:02:39
User entered 'No (N)'	System	18 Dec 2020 19:02:39

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-18T13:02:36', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '26ea295e-a2c8-404f-a145-a3fa628773f2' User entered '18 Dec 2020 13:02:36'	System	18 Dec 2020 19:02:39
	System	18 Dec 2020 19:02:39



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-24T09:30:35', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6edff03a-bc50-4a8e-a57a-6d378d121c48'	System	24 Dec 2020 15:30:42
User entered 'No (N)'	System	24 Dec 2020 15:30:42

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-24T09:30:37', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6edff03a-bc50-4a8e-a57a-6d378d121c48'	System	24 Dec 2020 15:30:42
User entered 'No (N)'	System	24 Dec 2020 15:30:42

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-24T09:30:40', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6edff03a-bc50-4a8e-a57a-6d378d121c48'	System	24 Dec 2020 15:30:42
User entered '24 Dec 2020 09:30:40'	System	24 Dec 2020 15:30:42

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-30T09:05:04', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6f25c40b-41b2-48cb-ae63-98ca175ee6b4' User entered 'No (N)'	System	30 Dec 2020 15:05:25
	System	30 Dec 2020 15:05:25

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-30T09:05:19', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6f25c40b-41b2-48cb-ae63-98ca175ee6b4' User entered 'No (N)'	System	30 Dec 2020 15:05:25

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2020-12-30T09:05:21', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '6f25c40b-41b2-48cb-ae63-98ca175ee6b4' User entered '30 Dec 2020 09:05:21'	System	30 Dec 2020 15:05:25
	System	30 Dec 2020 15:05:25

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-08T09:01:13', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '8ee554d8-2f5e-4f29-987b-155edecd300b'	System	08 Jan 2021 15:01:22
User entered 'No (N)'	System	08 Jan 2021 15:01:22



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-08T09:01:16', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '8ee554d8-2f5e-4f29-987b-155edecd300b'	System	08 Jan 2021 15:01:22
User entered 'No (N)'	System	08 Jan 2021 15:01:22

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-08T09:01:18', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '8ee554d8-2f5e-4f29-987b-155edecdc300b' User entered '08 Jan 2021 09:01:18'	System	08 Jan 2021 15:01:22
	System	08 Jan 2021 15:01:22

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-15T12:19:09', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cd036e50-1eb4-4083-8401-5e2d2b7759f5'	System	15 Jan 2021 18:19:18
User entered 'No (N)'	System	15 Jan 2021 18:19:18

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-15T12:19:11', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cd036e50-1eb4-4083-8401-5e2d2b7759f5'	System	15 Jan 2021 18:19:18
User entered 'No (N)'	System	15 Jan 2021 18:19:18

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-15T12:19:14', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'cd036e50-1eb4-4083-8401-5e2d2b7759f5' User entered '15 Jan 2021 12:19:14'	System	15 Jan 2021 18:19:18
	System	15 Jan 2021 18:19:18



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-20T00:01:48', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '14a12dc3-21ed-4bfd-90e8-634faf54b666'	System	20 Jan 2021 06:02:03
User entered 'No (N)'	System	20 Jan 2021 06:02:03

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-20T00:01:51', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '14a12dc3-21ed-4bfd-90e8-634faf54b666'	System	20 Jan 2021 06:02:03
User entered 'No (N)'	System	20 Jan 2021 06:02:03

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-20T00:01:54', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '14a12dc3-21ed-4bfd-90e8-634faf54b666'	System	20 Jan 2021 06:02:03
User entered '20 Jan 2021 00:01:54'	System	20 Jan 2021 06:02:03

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-29T12:21:26', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a7139c20-55b0-4ce1-8172-14e006eefc60'	System	29 Jan 2021 18:21:34
User entered 'No (N)'	System	29 Jan 2021 18:21:34

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-29T12:21:29', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a7139c20-55b0-4ce1-8172-14e006eefc60'	System	29 Jan 2021 18:21:34
User entered 'No (N)'	System	29 Jan 2021 18:21:34

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-01-29T12:21:31', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a7139c20-55b0-4ce1-8172-14e006eefc60' User entered '29 Jan 2021 12:21:31'	System	29 Jan 2021 18:21:34
	System	29 Jan 2021 18:21:34

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-03T00:06:18', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'ffab1106-1e90-4150-be89-bf160522ed19' User entered 'No (N)'	System	03 Feb 2021 06:06:26
	System	03 Feb 2021 06:06:26



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-03T00:06:20', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'ffab1106-1e90-4150-be89-bf160522ed19'	System	03 Feb 2021 06:06:26
User entered 'No (N)'	System	03 Feb 2021 06:06:26

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-03T00:06:24', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'ffab1106-1e90-4150-be89-bf160522ed19' User entered '03 Feb 2021 00:06:24'	System	03 Feb 2021 06:06:26
	System	03 Feb 2021 06:06:26

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-10T11:27:56', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'bb049b21-ea2f-4ae0-b0f1-6428fe5de304'	System	10 Feb 2021 17:28:29
User entered 'No (N)'	System	10 Feb 2021 17:28:29

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-10T11:27:58', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'bb049b21-ea2f-4ae0-b0f1-6428fe5de304'	System	10 Feb 2021 17:28:29
User entered 'No (N)'	System	10 Feb 2021 17:28:29

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-10T11:28:01', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'bb049b21-ea2f-4ae0-b0f1-6428fe5de304'	System	10 Feb 2021 17:28:29
User entered '10 Feb 2021 11:28:01'	System	10 Feb 2021 17:28:29



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-19T11:18:45', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5cc04ff7-cc9a-4dfd-ab18-98a7039d31a0' User entered 'No (N)'	System	19 Feb 2021 17:22:15
	System	19 Feb 2021 17:22:15

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-19T11:18:47', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5cc04ff7-cc9a-4dfd-ab18-98a7039d31a0' User entered 'No (N)'	System	19 Feb 2021 17:22:15
	System	19 Feb 2021 17:22:15

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-19T11:18:49', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '5cc04ff7-cc9a-4dfd-ab18-98a7039d31a0' User entered '19 Feb 2021 11:18:49'	System	19 Feb 2021 17:22:15
	System	19 Feb 2021 17:22:15

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-24T13:06:50', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '89a468d6-c1f1-4c8d-9c69-4e1e59152679' User entered 'Yes (Y)'	System	24 Feb 2021 19:07:32
	System	24 Feb 2021 19:07:32

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-24T13:06:53', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '89a468d6-c1f1-4c8d-9c69-4e1e59152679' User entered 'No (N)'	System	24 Feb 2021 19:07:32
	System	24 Feb 2021 19:07:32

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-24T13:06:56', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '89a468d6-c1f1-4c8d-9c69-4e1e59152679' User entered 'No (N)'	System	24 Feb 2021 19:07:32
	System	24 Feb 2021 19:07:32

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-24T13:07:02', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '89a468d6-c1f1-4c8d-9c69-4e1e59152679' User entered 'Yes (Y)'	System	24 Feb 2021 19:07:32
	System	24 Feb 2021 19:07:32

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Please 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-24T13:07:13', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '89a468d6-c1f1-4c8d-9c69-4e1e59152679'	System	24 Feb 2021 19:07:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Feb 2021 19:07:32

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-02-24T13:07:16', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '89a468d6-c1f1-4c8d-9c69-4e1e59152679' User entered '24 Feb 2021 13:07:16'	System	24 Feb 2021 19:07:32
	System	24 Feb 2021 19:07:32

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-03T10:59:36', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0cb73f2-55fd-403f-9d6c-76b7ec66e35f' User entered 'No (N)'	System	03 Mar 2021 16:59:51
	System	03 Mar 2021 16:59:51

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-03T10:59:38', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0cb73f2-55fd-403f-9d6c-76b7ec66e35f' User entered 'No (N)'	System	03 Mar 2021 16:59:51
	System	03 Mar 2021 16:59:51

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-03T10:59:41', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f0cb73f2-55fd-403f-9d6c-76b7ec66e35f' User entered '03 Mar 2021 10:59:41'	System	03 Mar 2021 16:59:51
	System	03 Mar 2021 16:59:51

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-12T13:19:05-06:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c9698c82-b1da-4419-a967-77148f5df585'	System	12 Mar 2021 19:19:19
User entered 'No (N)'	System	12 Mar 2021 19:19:19

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-12T13:19:08-06:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c9698c82-b1da-4419-a967-77148f5df585'	System	12 Mar 2021 19:19:19
User entered 'No (N)'	System	12 Mar 2021 19:19:19

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-12T13:19:13-06:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'c9698c82-b1da-4419-a967-77148f5df585'	System	12 Mar 2021 19:19:19
User entered '12 Mar 2021 13:19:13'	System	12 Mar 2021 19:19:19

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-17T00:11:24-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '27813b21-32ff-4791-9de8-1f79874c1ef7'	System	17 Mar 2021 05:11:30
User entered 'No (N)'	System	17 Mar 2021 05:11:30

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-17T00:11:26-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '27813b21-32ff-4791-9de8-1f79874c1ef7'	System	17 Mar 2021 05:11:30
User entered 'No (N)'	System	17 Mar 2021 05:11:30



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-17T00:11:29-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '27813b21-32ff-4791-9de8-1f79874c1ef7'	System	17 Mar 2021 05:11:30
User entered '17 Mar 2021 00:11:29'	System	17 Mar 2021 05:11:30

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-25T16:24:05-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '1317dac7-abff-4c77-86e4-88b36be1c80d' User entered 'No (N)'	System	25 Mar 2021 21:24:12
	System	25 Mar 2021 21:24:12

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-25T16:24:07-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '1317dac7-abff-4c77-86e4-88b36be1c80d'	System	25 Mar 2021 21:24:12
User entered 'No (N)'	System	25 Mar 2021 21:24:12

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-25T16:24:09-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '1317dac7-abff-4c77-86e4-88b36be1c80d'	System	25 Mar 2021 21:24:12
User entered '25 Mar 2021 16:24:09'	System	25 Mar 2021 21:24:12

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-31T11:19:36-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fb88cf99-2ae6-4cf8-9e44-5e6f221e732f' User entered 'No (N)'	System	31 Mar 2021 16:22:33
	System	31 Mar 2021 16:22:33

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-31T11:19:38-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fb88cf99-2ae6-4cf8-9e44-5e6f221e732f'	System	31 Mar 2021 16:22:33
User entered 'No (N)'	System	31 Mar 2021 16:22:33

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-31T11:19:40-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'fb88cf99-2ae6-4cf8-9e44-5e6f221e732f' User entered '31 Mar 2021 11:19:40'	System	31 Mar 2021 16:22:33
	System	31 Mar 2021 16:22:33

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-04-07T01:23:09-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a384bb29-3b12-4e28-bd5e-056e90cc8be7' User entered 'No (N)'	System	07 Apr 2021 06:23:18
	System	07 Apr 2021 06:23:18

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-04-07T01:23:13-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a384bb29-3b12-4e28-bd5e-056e90cc8be7'	System	07 Apr 2021 06:23:18
User entered 'No (N)'	System	07 Apr 2021 06:23:18

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-04-07T01:23:16-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'a384bb29-3b12-4e28-bd5e-056e90cc8be7'	System	07 Apr 2021 06:23:18
User entered '07 Apr 2021 01:23:16'	System	07 Apr 2021 06:23:18

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-04-29T10:38:37-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f996e29b-65e7-48f9-abc3-afc6fcc1f0b8'	System	29 Apr 2021 15:39:03
User entered 'No (N)'	System	29 Apr 2021 15:39:03

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Have you been exposed to someone with 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 (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-04-29T10:38:39-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f996e29b-65e7-48f9-abc3-afc6fcc1f0b8'	System	29 Apr 2021 15:39:03
User entered 'No (N)'	System	29 Apr 2021 15:39:03

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-04-29T10:38:41-05:00', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: 'f996e29b-65e7-48f9-abc3-afc6fcc1f0b8'	System	29 Apr 2021 15:39:03
User entered '29 Apr 2021 10:38:41'	System	29 Apr 2021 15:39:03

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:59:41



**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 10:59:41

**US3002329**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:52:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:41
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 10:59:41

US3002329

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:52:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:30:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-03T10:59:48', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '100670c9-616a-4691-b829-fef91172a8c5'	System	03 Mar 2021 16:59:59
User entered 'No (N)'	System	03 Mar 2021 16:59:59

**US3002329**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:30:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EA833980-680E-434C-9358-721FA680743C)', Time: '2021-03-03T10:59:53', User OID: 'PatientReportedOutcome (US3002329)', ODM File OID: '100670c9-616a-4691-b829-fef91172a8c5' User entered '03 Mar 2021 10:59:53'	System	03 Mar 2021 16:59:59
	System	03 Mar 2021 16:59:59

**US3002329**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	12 Jan 2021 03:31:23

**US3002329**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '22 Dec 2020'	Jessica Satorie (b) (4)	12 Jan 2021 03:31:23

**US3002329**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Contact Made (CONTACT MADE)'	Jessica Satorie (b) (4)	12 Jan 2021 03:31:23

**US3002329**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) Jessica Satorie (b) (4)	12 Jan 2021 03:31:23
	(b) (4)	



**US3002329**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	12 Jan 2021 03:31:40

**US3002329**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:07:31
User entered 'I'	System	12 Jan 2021 03:31:40

**US3002329**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:59:26

**US3002329**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '25 Jan 2021'	(b) (4), (b) (6)	02 Feb 2021 19:59:26

**US3002329**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Feb 2021 19:59:26

**US3002329**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:59:26

**US3002329**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:59:31

**US3002329**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User entered 'I'	System	02 Feb 2021 19:59:31



**US3002329**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 18:48:29

**US3002329**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:54:56
User entered '02 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 18:48:29

**US3002329**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:54:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Mar 2021 18:48:29

**US3002329**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:52:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:54:56
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 18:48:29

**US3002329**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 18:48:33

**US3002329**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:30:59
User entered '1'	System	11 Mar 2021 18:48:33

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 14:49:26

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 14:49:26



**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Jan 2021 14:49:26

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:52:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 14:49:26

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 14:49:53

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:54:56
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:18:14

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 14:49:53

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:54:56
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:18:14

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 14:49:53

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 14:49:53



**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 14:49:53

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 14:49:53

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 14:49:53

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User entered empty.	System	28 Jan 2021 14:49:53

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:52:37**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User entered empty.	System	28 Jan 2021 14:49:53

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 14:50:10

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 14:50:10

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:25'	(b) (4), (b) (6)	28 Jan 2021 14:50:10



**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:52:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User entered '28 Jan 2021 08:25'	System	28 Jan 2021 14:50:10

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:52:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 14:50:18

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:52:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 14:50:18

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:52:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '08:22'	(b) (4), (b) (6)	28 Jan 2021 14:50:18

**US3002329**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:52:37**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:46:45
User entered '28 Jan 2021 08:22'	System	28 Jan 2021 14:50:18

US3002329

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:52:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM, DM CLR RQ: Response " subject reported she is pregnant at this phone call" is noted. Please confirm the subject will remain in study for follow-up (even if intended duration of safety follow-up for study has ended) as Pregnancy report forms are to be used for this purpose. Kindly follow procedures outlined in section 8.3.5. of Protocol Amendment 7 and confirm pregnancy is reported as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 06:10:10
Query 'Per CDM, DM CLR RQ: Response " subject reported she is pregnant at this phone call" is noted. Please confirm the subject will remain in study for follow-up (even if intended duration of safety follow-up for study has ended) as Pregnancy report forms are to be used for this purpose. Kindly follow procedures outlined in section 8.3.5. of Protocol Amendment 7 and confirm pregnancy is reported as appropriate. ' answered with 'Patient is willing to continue in the study for safety follow up phone calls. She is not willing to come for visits. She will continue to do her diary. Pregnancy was reported to the safety_moderna on 2/26/2021.' (Site from DM).	Jessica Satorie (b) (4)	29 Apr 2021 16:31:36
User opened query 'Per CDM, DM CLR RQ: Response " subject reported she is pregnant at this phone call" is noted. Please confirm the subject will remain in study for follow-up (even if intended duration of safety follow-up for study has ended) as Pregnancy report forms are to be used for this purpose. Kindly follow procedures outlined in section 8.3.5. of Protocol Amendment 7 and confirm pregnancy is reported as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:28:04

US3002329

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:52:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Day 152 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)	30 Mar 2021 14:28:04
Query 'Per DM CLR: Per Day 152 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 'subject reported she is pregnant at this phone call' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	26 Mar 2021 19:56:37
User opened query 'Per DM CLR: Per Day 152 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)	24 Mar 2021 13:14:17
User signature succeeded.	Brandon Essink (b) (4) (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 16:43:11

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 21:52:37**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:50:45
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 16:43:25



US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;LEVONORGESTREL, PRODUCTSYNONYM: LUTERA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 11:29:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 11:29:48
Data point term sent to Coder	System	28 Sep 2020 16:44:39
User entered 'Lutera Levonorgestrel/ethinyl estradiol'	(b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Contraception'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0.1/0.02'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

US3002329

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:52:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25



**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

US3002329

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:44:25



**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:44:25

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:52:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 16:44:25

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 23:11:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 23:11:50
Data point term sent to Coder	System	18 Nov 2020 23:10:43
User entered 'tylenol'	Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User closed query 'Per DM CLR-RQ: Response note. However, injection Site Pain is recorded on Day 2 (31 Oct) only. Please review indication and review if this should be recorded as unsolicited AE. Review and update entries. Else, re-clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Brandon Essink (b) (4)	18 Feb 2021 11:08:51 15 Feb 2021 22:19:19
Query 'Per DM CLR-RQ: Response note. However, injection Site Pain is recorded on Day 2 (31 Oct) only. Please review indication and review if this should be recorded as unsolicited AE. Review and update entries. Else, re-clarify.' answered with 'staff error corrected' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	03 Feb 2021 19:44:19
User opened query 'Per DM CLR-RQ: Response note. However, injection Site Pain is recorded on Day 2 (31 Oct) only. Please review indication and review if this should be recorded as unsolicited AE. Review and update entries. Else, re-clarify.' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 05:37:49
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 05:37:49
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'subjected recorded injection site pain on diary for this date.' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	06 Jan 2021 16:34:19
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 09:39:24
User entered 'injection site pain'	Kimberly Mueller (b) (4) (b) (4)	18 Nov 2020 23:10:40

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EAB) (1725)

1540 of 1556

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '650'	(b) (4) Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'mg (mg)'	Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40



**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'once (ONCE)'	Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40
	(b) (4)	

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Oral (ORAL)'	Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

US3002329

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:52:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered empty.	(b) (4) Kimberly Mueller (b) (4) (b) (4)	18 Nov 2020 23:10:40

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Kimberly Mueller (b) (4)	03 Feb 2021 19:44:09
User entered '01 Nov 2020'	(b) (4)	
	Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40
	(b) (4)	

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '0'	Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Kimberly Mueller (b) (4)	03 Feb 2021 19:44:09
User entered '01 Nov 2020'	(b) (4)	
	Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40
	(b) (4)	



**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	18 Nov 2020 23:10:40

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User entered empty.	System	18 Nov 2020 23:10:40

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User entered empty.	System	18 Nov 2020 23:10:40

**US3002329**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:52:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 05:09:11
User entered empty.	System	18 Nov 2020 23:10:40

US3002329

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 21:52:37**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	15 Feb 2021 22:19:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 16:43:19