

US3402300 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:35:15

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US3402300

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

[Participant ID](#)

US3402300

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

US3402300

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

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

Visit date (dd MMM yyyy)	08 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3402300

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:50:19

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Date of Informed Consent (<i>dd MMM yyyy</i>)	8 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:50:19

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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 17:50:19

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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 17:50:19

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Condition	FACTOR V LEIDEN
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
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 17:50:19

Generated On: 11 Aug 2021 22:35:15

Condition	OTOSCLEROSIS RIGHT EAR
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:50:19

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:44 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 13:44
Height (<i>xxx.x</i>)	166.7 cm
Weight (<i>xxx.x</i>)	68.7 kg
BMI (<i>xxx.x</i>)	24.72211 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 AUG 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 17:50:19

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Date of assessment (dd MMM yyyy) 8 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:50:19

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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>)	8 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:50:19

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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 ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:50:19

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 102390

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 17:50:19

Generated On: 11 Aug 2021 22:35:15

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 17:50:19

Generated On: 11 Aug 2021 22:35:15

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)	8 AUG 2020
Time of assessment (00:00-23:59)	13:44 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 13:44
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 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 17:50:19

Generated On: 11 Aug 2021 22:35:15

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)	8 AUG 2020
Time of assessment (00:00-23:59)	14:54 (24 HR)
Vital Signs Date and Time (derived)	8 AUG 2020 14:54
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

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 17:50:19

Generated On: 11 Aug 2021 22:35:15

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) 8 AUG 2020

What was the treatment time? (00:00-23:59) 14:23 (24 HR)

Treatment Date and Time (derived) 8 AUG 2020 14:23

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 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 AUG 2020

Collection time (00:00-23:59)

14:10 (24 HR)

Collection date and time (derived)

8 AUG 2020 14:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Collection date (dd MMM yyyy)			8 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:07	8 AUG 2020 14:07
Nasopharyngeal Swab 2	No		

US3402300

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.1 °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 08 AUG 2020 14:55

PC Open Date & Time 08 AUG 2020 14:43

PC Close Date & Time 08 AUG 2020 17:13

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

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 96.4 °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	08 AUG 2020 22:47
PC Open Date & Time	08 AUG 2020 18:08
PC Close Date & Time	09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☒

No ☐

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

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 AUG 2020 20:05

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:15

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 10:20

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 08:22

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:15

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

13 AUG 2020 08:14

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

13 AUG 2020 18:19

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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

15 AUG 2020 07:59

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 14:56

PC Open Date & Time

08 AUG 2020 14:43

PC Close Date & Time

08 AUG 2020 17:13

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 22:48

PC Open Date & Time

08 AUG 2020 18:08

PC Close Date & Time

09 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 20:07

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

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

11 AUG 2020 10:20

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

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

12 AUG 2020 08:23

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

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

13 AUG 2020 08:15

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

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

13 AUG 2020 18:20

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

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

15 AUG 2020 07:59

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 14:56
PC Open Date & Time	08 AUG 2020 14:43
PC Close Date & Time	08 AUG 2020 17:13

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 22:48
PC Open Date & Time	08 AUG 2020 18:08
PC Close Date & Time	09 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

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 ☒

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EAB) (1725)

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:08
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

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 ☒

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 10:21
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 08:23
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 08:15
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

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 ☐

PRODUCTION RELEASE (v12.003

54 of 1607

EAB) (1725)

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

		Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 18:21	
PC Open Date & Time	13 AUG 2020 12:00	
PC Close Date & Time	14 AUG 2020 11:59	

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 08:00
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3402300

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:50:20

Generated On: 11 Aug 2021 22:35:15

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)	9 SEP 2020
Time of assessment (00:00-23:59)	09:13 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 09:13
Temperature (xxx.x)	97.8 F
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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:50:20

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	9 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)	

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

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 HERPES SIMPLEX

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3402300

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 SEP 2020

Collection time (00:00-23:59)

09:33 (24 HR)

Collection date and time (derived)

9 SEP 2020 09:33

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:31	9 SEP 2020 09:31
Nasopharyngeal Swab 2	No		

US3402300

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:19

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:50:20

Generated On: 11 Aug 2021 22:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:50:20

Generated On: 11 Aug 2021 22:35:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:36 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:36
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402300

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:50:20

Generated On: 11 Aug 2021 22:35:15

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.

US3402300

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:50:20

Generated On: 11 Aug 2021 22:35:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

10:42 (24 HR)

Collection date and time (derived)

8 OCT 2020 10:42

US3402300

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:50:20

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 19:39:45

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 08:24:07

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 17:59:32

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 07:36:58
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

20 NOV 2020 18:06:58

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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	23 NOV 2020 14:54:34
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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	09 DEC 2020 12:03:11
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 07:41:38
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 06:48:30

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

28 DEC 2020 07:56:59

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 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"/>
Have 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 checked="" 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)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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	04 JAN 2021 08:19:08
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

14 JAN 2021 17:59:49

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 12:12:22
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 12:02:12

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 05:30:41
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 187

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

08 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 07:54:10
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 07:09:22
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 14:06:01

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

08 MAR 2021 11:51:33

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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="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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 07:23:14

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 MAR 2021 07:18:39

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 12:00:44

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 19:05:26

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 19:40:43

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 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	03 MAY 2021 07:35:44
Patient Cloud Open Date & Time	03 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	07 JUN 2021 00:01
Patient Cloud Close Date & Time	11 JUN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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="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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 383

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 425

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

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

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

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

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

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

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 NOV 2021 00:01
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Patient Cloud Close Date & Time	19 NOV 2021 23:59
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US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 474

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

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

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

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

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

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

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 481

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

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

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

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

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

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

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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°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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	27 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	14 MAR 2022 00:01
Patient Cloud Close Date & Time	18 MAR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 628

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

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

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

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

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

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

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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 ☐

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 691

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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="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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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="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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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="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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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"/>

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

US3402300

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:35:15

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 14:06:13

US3402300

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:25:32

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:25:32

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:06:57

Generated On: 11 Aug 2021 22:35:15

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

Visit date (dd MMM yyyy)	11 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:06:57

Generated On: 11 Aug 2021 22:35:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 10:45
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:06:57

Generated On: 11 Aug 2021 22:35:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3402300

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:06:57

Generated On: 11 Aug 2021 22:35:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	10:24 (24 HR)
Collection date and time (derived)	11 MAR 2021 10:24

US3402300

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:57

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402300

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:35:15

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402300

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

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

Visit date (dd MMM yyyy)	11 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3402300

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	11 MAR 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3402300

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3402300

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 10:45
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3402300

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 11:55
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3402300

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3402300

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

Form: Pregnancy Test

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 11 MAR 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3402300

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 MAR 2021

What was the treatment time? (00:00-23:59) 11:23 (24 HR)

Treatment Date and Time (derived) 11 MAR 2021 11:23

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

US3402300

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 MAR 2021

Collection time (00:00-23:59)

10:24 (24 HR)

Collection date and time (derived)

11 MAR 2021 10:24

US3402300

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

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

Collection date (dd MMM yyyy)	11 MAR 2021
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Collection time (00:00 - 23:59)	10:21
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Collection Date and Time (derived)	11 MAR 2021 10:21
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US3402300

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402300

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402300

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:06:27

Generated On: 11 Aug 2021 22:35:15

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3402300

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3402300

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

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.

US3402300

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 APR 2021

Collection time (00:00-23:59)

09:32 (24 HR)

Collection date and time (derived)

13 APR 2021 09:32

US3402300

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:44:41

Generated On: 11 Aug 2021 22:35:15

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 00:04:16

Generated On: 11 Aug 2021 22:35:15

AEID	
Adverse event	HERPES SIMPLEX
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 00:04:16

Generated On: 11 Aug 2021 22:35:15

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

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 11 Aug 2021 22:35:15

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

Yes ☒

No ☐

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

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 11 Aug 2021 22:35:15

Name of Medication VALTREX (VALCYCLOVIR)

Prophylaxis Yes ☐
No ☒

Indication HERPES SIMPLEX

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 11 Aug 2021 22:35:15

	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)	13 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	28 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 11 Aug 2021 22:35:15

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 11 Aug 2021 22:35:15

	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)	09 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 11 Aug 2021 22:35:15

Name of Medication TETANUS VACCINE

Prophylaxis Yes ☒
No ☐

Indication TETANUS PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 11 Aug 2021 22:35:15

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3402300

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:36:48

Generated On: 11 Aug 2021 22:35:15

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3402300

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Apr 2021 23:06:26

Generated On: 11 Aug 2021 22:35:15

Date of dosing discontinuation (dd MMM yyyy)	9 SEP 2020
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Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #1
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US3402300

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:15

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

US3402300 (Prod: Meridian Clinical Research, LLC)

US3402300

Form: Participant Creation

Generated On: 11 Aug 2021 22:35:15

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'US3402300'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:00:23

US3402300

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4)	Jennifer Molstead (b) (4) 08 Aug 2020 18:40:37
	(b) (4)	

US3402300

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:00:25

US3402300

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	08 Aug 2020 18:40:37

US3402300

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'SCRN'	System	08 Aug 2020 18:40:37

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered (b) (6) 1976'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:00:26

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '44'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'YEARS'	System	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered '44'	System	08 Aug 2020 18:41:08

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Female (F)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'I'	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:42:01
	(b) (4)	

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:15

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:42:01

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Jennifer Molstead (b) (4)	08 Aug 2020 18:41:08

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'Aug 2020'	System	08 Aug 2020 18:41:08

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered '2020'	System	08 Aug 2020 18:41:08

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Amendment 2 (2)'	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:08

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4)	
	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:08
	(b) (4)	

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:08
	(b) (4)	

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:08
	(b) (4)	

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4)	
	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:08
	(b) (4)	

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:00:25

US3402300

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'I'	System	08 Aug 2020 18:41:14

US3402300

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4)	Jennifer Molstead (b) (4) 08 Aug 2020 18:41:14
	(b) (4)	

US3402300

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:35:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:43:27

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Coagulation disorders congenital, PT: Factor V Leiden mutation, LLT: Factor V Leiden mutation - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 12:45:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Aug 2020 12:45:27
Data point term sent to Coder	System	09 Aug 2020 12:44:20
User entered 'FACTOR V LEIDEN'	Tarin Gordon (b) (4)	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'UN UNK 2008'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:43:50
	(b) (4)	

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'Jan 2008'	System	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered '2008'	System	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered empty.	System	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered empty.	System	09 Aug 2020 12:43:50

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Middle ear disorders (excl congenital), HLT: Middle ear disorders NEC, PT: Otosclerosis, LLT: Otosclerosis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 14:04:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Aug 2020 14:04:32
Data point term sent to Coder	System	09 Aug 2020 12:48:20
User entered 'OTOSCLEROSIS RIGHT EAR'	Tarin Gordon (b) (4)	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'UN UNK 2008'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'Jan 2008'	System	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered '2008'	System	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered empty.	System	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered empty.	System	09 Aug 2020 12:47:37

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
	(b) (4)	

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:49:17

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '13:44'	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
	(b) (4)	

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered '8 Aug 2020 13:44'	System	09 Aug 2020 12:49:17

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '166.7' cm	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
DataPoint set to visible.	(b) (4)	
	System	08 Aug 2020 18:41:14

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '68.7' kg	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
DataPoint set to visible.	(b) (4)	
	System	08 Aug 2020 18:41:14

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
Amendment Manager: User entered '24.72211'	System	16 Sep 2020 23:48:58
User entered '24.7'	System	09 Aug 2020 12:49:17
DataPoint set to visible.	System	08 Aug 2020 18:41:14

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'kg/m2'	System	09 Aug 2020 12:49:17
DataPoint set to visible.	System	08 Aug 2020 18:41:14

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:05:48
User entered '98.2' F	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
	(b) (4)	

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	20 Dec 2020 18:05:48
	(b) (4)	
User entered 'Oral (Oral)'	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
	(b) (4)	

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:49:17

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:05:48
User entered '82'	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
	(b) (4)	

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'bpm'	System	09 Aug 2020 12:49:17

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:05:48
User entered '14'	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
	(b) (4)	

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'breaths/min'	System	09 Aug 2020 12:49:17

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:05:48
User entered '128'	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
	(b) (4)	

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'mmHg'	System	09 Aug 2020 12:49:17

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:05:48
User entered '78'	Tarin Gordon (b) (4)	09 Aug 2020 12:49:17
	(b) (4)	

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered 'mmHg'	System	09 Aug 2020 12:49:17

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46

US3402300

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46

US3402300

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:49:37
	(b) (4)	

US3402300

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:32:58
Comment added 'SAME DATE'.	Traci Hull (b) (4)	11 Sep 2020 18:43:17
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Sep 2020 18:43:05
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 18:43:05
User entered '08 Aug 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	11 Sep 2020 18:43:05
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	09 Sep 2020 17:20:14
User entered '8 Aug 2020'	Tarin Gordon (b) (4)	09 Aug 2020 12:49:37
	(b) (4)	

US3402300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:49:58

US3402300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:49:58

US3402300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:49:58
	(b) (4)	

US3402300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:15

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:49:58

US3402300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:49:58
	(b) (4)	

US3402300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:15

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:49:58

US3402300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:49:58

US3402300

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:15

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:49:58

US3402300

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:50:29

US3402300

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:50:29

US3402300

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Urine (URINE)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:50:29

US3402300

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Negative (NEGATIVE)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:50:29

US3402300

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:50:29
	(b) (4)	

US3402300

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:50:29
	(b) (4)	

US3402300

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:50:29

US3402300

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User entered empty.	System	09 Aug 2020 12:50:29

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05
	(b) (4)	

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05
	(b) (4)	

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05
	(b) (4)	

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

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)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'I'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '0'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:05

US3402300

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:36:46
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:51:05
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:19

US3402300

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:19

US3402300

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:19

US3402300

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'VISIT1'	System	09 Aug 2020 12:51:19

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:00:28

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:08:09
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:08:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 18:00:28
User entered '102390' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:00:28

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 18:00:28

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:31

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:51:31

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:31

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:31

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:51:31

US3402300

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:15

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:56:38
User entered 'No (N)'	Tammy Kohn (b) (4)	02 Nov 2020 13:21:29
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Amendment Manager: DataPoint set to visible.	Tammy Kohn (b) (4)	02 Nov 2020 13:21:22
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	02 Nov 2020 10:47:36
	System	19 Sep 2020 10:04:05
	System	19 Sep 2020 04:38:21

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:06:06
User entered '166.7' cm	Tarin Gordon (b) (4)	09 Aug 2020 12:53:01
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:06:06
User entered '68.7' kg	Tarin Gordon (b) (4)	09 Aug 2020 12:53:01
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:06:06
User entered '166.7' cm	Tarin Gordon (b) (4)	09 Aug 2020 12:53:01
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:06:06
User entered '68.7' kg	Tarin Gordon (b) (4)	09 Aug 2020 12:53:01
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '13:44'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered '8 Aug 2020 13:44'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '98.2' F	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '82'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'bpm'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '14'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'breaths/min'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '128'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'mmHg'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '78'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'mmHg'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:06:06
User entered '166.7' cm	Tarin Gordon (b) (4)	09 Aug 2020 12:53:01
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 18:06:06
User entered '68.7' kg	Tarin Gordon (b) (4)	09 Aug 2020 12:53:01
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Aug 2020 12:58:02
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN' (Site from System).	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 12:53:12
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		09 Aug 2020 12:53:01
User entered '14:54'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered '8 Aug 2020 14:54'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '97.1' F	(b) (4)	
	Tarin Gordon (b) (4)	09 Aug 2020 12:53:01
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '65'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'bpm'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '14'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'breaths/min'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '115'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'mmHg'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '77'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'mmHg'	System	09 Aug 2020 12:53:01

US3402300

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:24

US3402300

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:24

US3402300

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:03:12
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:31:20
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:31:16
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 09:24:41
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 12:53:36

US3402300

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	06 Oct 2020 11:31:16
	(b) (4)	
User entered '8 Aug 2020'	Tarin Gordon (b) (4)	09 Aug 2020 12:53:36
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	06 Oct 2020 11:31:16
	(b) (4)	
User entered 'Urine (URINE)'	Tarin Gordon (b) (4)	09 Aug 2020 12:53:36
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	06 Oct 2020 11:31:16
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Tarin Gordon (b) (4)	09 Aug 2020 12:53:36
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User closed query 'Per CDM: A yes/no response is required for this field. Please update. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 10:55:31
Query 'Per CDM: A yes/no response is required for this field. Please update. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	07 Oct 2020 19:51:59
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	07 Oct 2020 19:51:55
User opened query 'Per CDM: A yes/no response is required for this field. Please update. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 18:03:16
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	06 Oct 2020 11:31:16
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 12:53:36

US3402300

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:36

US3402300

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:36

US3402300

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered empty.	System	09 Aug 2020 12:53:36

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '14:23'	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered '8 Aug 2020 14:23'	System	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'ONCE'	System	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 18:41:51

US3402300

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:57

US3402300

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:57

US3402300

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '14:10'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:53:57

US3402300

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered '8 Aug 2020 14:10'	System	09 Aug 2020 12:53:57

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 05:45:14
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number and the shipment tracking details in the response. Thank you.' answered with 'FedEX. AWB# 906907844584 Delivered Wednesday, August 12, 2020 at 8:47 am DELIVERED Signed for by: (b) (6) ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	17 Mar 2021 14:41:00
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:12:49
User closed query 'Per GCL Lab Reconciliation: Swab: Per site response," RECONCILIATION PAPERWORK SENT TO PPD BY LAB PERSONNEL"; however, no updates are reflected in PPD portal. Please review if the sample has been shipped then provide Accession and tracking number and shipped date or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:12:49
Query 'Per GCL Lab Reconciliation: Swab: Per site response," RECONCILIATION PAPERWORK SENT TO PPD BY LAB PERSONNEL"; however, no updates are reflected in PPD portal. Please review if the sample has been shipped then provide Accession and tracking number and shipped date or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Shipped 11AUG2020 AWB# 906907844584 FedEX ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	11 Mar 2021 17:14:15

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:35:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Per site response," RECONCILIATION PAPERWORK SENT TO PPD BY LAB PERSONNEL"; however, no updates are reflected in PPD portal. Please review if the sample has been shipped then provide Accession and tracking number and shipped date or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:49:22
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-AUG-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	21 Dec 2020 04:17:27
' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-AUG-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	Tammy Kohn (b) (4) (b) (4)	19 Dec 2020 16:45:36
' answered with 'RECONCILIATION PAPERWORK SENT TO PPD BY LAB PERSONNEL' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-AUG-2020 is recorded under Visit 1 Day 1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.	(b) (4), (b) (6)	07 Dec 2020 05:16:41
' (Site from DM). User entered '8 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 12:54:11

PRODUCTION RELEASE (v12.003
EAB) (1725)

511 of 1607

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4)	09 Aug 2020 12:54:11

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:54:11

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '14:07'	(b) (4)	09 Aug 2020 12:54:11
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered '8 Aug 2020 14:07'	System	09 Aug 2020 12:54:11

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 12:54:11

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:54:11

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:54:11

US3402300

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered empty.	System	09 Aug 2020 12:54:11

US3402300

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	09 Aug 2020 12:54:18

US3402300

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:12:10
User entered '1'	System	09 Aug 2020 12:54:18

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:54:44', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '76216c90-8a78-4dea-b53f-c86a186eb59e' User entered 'Yes (Y)'	System	08 Aug 2020 18:55:09
	System	08 Aug 2020 18:55:09

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:54:52', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '76216c90-8a78-4dea-b53f-c86a186eb59e' User entered '97.1'	System	08 Aug 2020 18:55:09
	System	08 Aug 2020 18:55:09

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:54:57', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '76216c90-8a78-4dea-b53f-c86a186eb59e' User entered 'No (N)'	System	08 Aug 2020 18:55:09
	System	08 Aug 2020 18:55:09

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:55:06', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '76216c90-8a78-4dea-b53f-c86a186eb59e' User entered '08 Aug 2020 14:55'	System	08 Aug 2020 18:55:09
	System	08 Aug 2020 18:55:09

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 14:43'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 17:13'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:47:08', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0c6351fc-f3e1-42a3-b9ab-c92237ea35bd' User entered 'Yes (Y)'	System	09 Aug 2020 02:47:23
	System	09 Aug 2020 02:47:23

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:47:13', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0c6351fc-f3e1-42a3-b9ab-c92237ea35bd' User entered '96.4'	System	09 Aug 2020 02:47:23
	System	09 Aug 2020 02:47:23

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:47:17', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0c6351fc-f3e1-42a3-b9ab-c92237ea35bd'	System	09 Aug 2020 02:47:23
User entered 'No (N)'	System	09 Aug 2020 02:47:23

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:47:20', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0c6351fc-f3e1-42a3-b9ab-c92237ea35bd' User entered '08 Aug 2020 22:47'	System	09 Aug 2020 02:47:23
	System	09 Aug 2020 02:47:23

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 18:08'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 2'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:04:57', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6846fe65-2744-40ca-ad1f-31b57a8419d6' User entered 'Yes (Y)'	System	10 Aug 2020 00:05:27
	System	10 Aug 2020 00:05:27

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:05:01', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6846fe65-2744-40ca-ad1f-31b57a8419d6' User entered '96.5'	System	10 Aug 2020 00:05:27
	System	10 Aug 2020 00:05:27

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:05:10', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6846fe65-2744-40ca-ad1f-31b57a8419d6'	System	10 Aug 2020 00:05:27
User entered 'Yes (Y)'	System	10 Aug 2020 00:05:27

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
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 'PATIENT TOOK IBUPROFEN FOR MILD INJECTION SITE PAIN' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 14:52:19
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).	Tammy Kohn (b) (4)	02 Oct 2020 20:51:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:05:18', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6846fe65-2744-40ca-ad1f-31b57a8419d6'	(b) (4)	
User entered '1'	System	10 Aug 2020 00:05:27
	System	10 Aug 2020 00:05:27
	System	10 Aug 2020 00:05:27

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:05:18', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6846fe65-2744-40ca-ad1f-31b57a8419d6' User entered '0'	System	10 Aug 2020 00:05:27
	System	10 Aug 2020 00:05:27

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:05:26', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6846fe65-2744-40ca-ad1f-31b57a8419d6' User entered '09 Aug 2020 20:05'	System	10 Aug 2020 00:05:27
	System	10 Aug 2020 00:05:27

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 3'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:19:58', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'dabc6489-4611-47a1-baa6-5e2d0f094146' User entered 'Yes (Y)'	System	11 Aug 2020 14:20:12
	System	11 Aug 2020 14:20:12

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:03', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'dabc6489-4611-47a1-baa6-5e2d0f094146' User entered '96.9'	System	11 Aug 2020 14:20:12
	System	11 Aug 2020 14:20:12

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:06', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'dabc6489-4611-47a1-baa6-5e2d0f094146'	System	11 Aug 2020 14:20:12
User entered 'No (N)'	System	11 Aug 2020 14:20:12

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:10', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'dabc6489-4611-47a1-baa6-5e2d0f094146' User entered '11 Aug 2020 10:20'	System	11 Aug 2020 14:20:12
	System	11 Aug 2020 14:20:12

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 4'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:22:29', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'e0eb7f5e-089f-4ebc-87c1-92477cfe635b' User entered 'Yes (Y)'	System	12 Aug 2020 12:22:46
	System	12 Aug 2020 12:22:46

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:22:35', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'e0eb7f5e-089f-4ebc-87c1-92477cfe635b' User entered '96.9'	System	12 Aug 2020 12:22:46
	System	12 Aug 2020 12:22:46

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:22:39', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'e0eb7f5e-089f-4ebc-87c1-92477cfe635b'	System	12 Aug 2020 12:22:46
User entered 'No (N)'	System	12 Aug 2020 12:22:46

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:22:44', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'e0eb7f5e-089f-4ebc-87c1-92477cfe635b' User entered '12 Aug 2020 08:22'	System	12 Aug 2020 12:22:46
	System	12 Aug 2020 12:22:46

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 5'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:15

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:14:13', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '5822979a-de82-444c-abac-d47b3f384665' User entered 'Yes (Y)'	System	13 Aug 2020 12:14:37
	System	13 Aug 2020 12:14:37

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:14:19', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '5822979a-de82-444c-abac-d47b3f384665' User entered '97.2'	System	13 Aug 2020 12:14:37
	System	13 Aug 2020 12:14:37

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:14:32', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '5822979a-de82-444c-abac-d47b3f384665' User entered 'No (N)'	System	13 Aug 2020 12:14:37
	System	13 Aug 2020 12:14:37

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:14:35', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '5822979a-de82-444c-abac-d47b3f384665' User entered '13 Aug 2020 08:14'	System	13 Aug 2020 12:14:37
	System	13 Aug 2020 12:14:37

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 6'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:19:23', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0e18f935-06af-449d-8e1a-1c13b2440b86'	System	13 Aug 2020 22:19:49
User entered 'Yes (Y)'	System	13 Aug 2020 22:19:49

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:19:37', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0e18f935-06af-449d-8e1a-1c13b2440b86' User entered '97.2'	System	13 Aug 2020 22:19:49
	System	13 Aug 2020 22:19:49

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:19:43', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0e18f935-06af-449d-8e1a-1c13b2440b86'	System	13 Aug 2020 22:19:49
User entered 'No (N)'	System	13 Aug 2020 22:19:49

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:19:46', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0e18f935-06af-449d-8e1a-1c13b2440b86'	System	13 Aug 2020 22:19:49
User entered '13 Aug 2020 18:19'	System	13 Aug 2020 22:19:49

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 7'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:27', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b1c09540-7c13-4f87-aa88-7ba7a128bc19' User entered 'Yes (Y)'	System	15 Aug 2020 11:59:41
	System	15 Aug 2020 11:59:41

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:30', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b1c09540-7c13-4f87-aa88-7ba7a128bc19' User entered '96.2'	System	15 Aug 2020 11:59:41
	System	15 Aug 2020 11:59:41

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:36', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b1c09540-7c13-4f87-aa88-7ba7a128bc19'	System	15 Aug 2020 11:59:41
User entered 'No (N)'	System	15 Aug 2020 11:59:41

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:38', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b1c09540-7c13-4f87-aa88-7ba7a128bc19' User entered '15 Aug 2020 07:59'	System	15 Aug 2020 11:59:41
	System	15 Aug 2020 11:59:41

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:55:21', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '03cd95a6-0c8e-45ec-9019-d8f0879b93ab' User entered 'None (1)'	System	08 Aug 2020 18:56:05
	System	08 Aug 2020 18:56:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:55:37', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '03cd95a6-0c8e-45ec-9019-d8f0879b93ab' User entered 'No (N)'	System	08 Aug 2020 18:56:05
	System	08 Aug 2020 18:56:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:55:45', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '03cd95a6-0c8e-45ec-9019-d8f0879b93ab' User entered 'No (N)'	System	08 Aug 2020 18:56:05
	System	08 Aug 2020 18:56:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:55:57', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '03cd95a6-0c8e-45ec-9019-d8f0879b93ab' User entered 'None (1)'	System	08 Aug 2020 18:56:05
	System	08 Aug 2020 18:56:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:03', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '03cd95a6-0c8e-45ec-9019-d8f0879b93ab' User entered '08 Aug 2020 14:56'	System	08 Aug 2020 18:56:05
	System	08 Aug 2020 18:56:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 14:43'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 17:13'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:47:35', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30927400-5a51-478a-8b83-09567cfbd307'	System	09 Aug 2020 02:48:33
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 02:48:33

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:10', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30927400-5a51-478a-8b83-09567cfbd307' User entered 'No (N)'	System	09 Aug 2020 02:48:33
	System	09 Aug 2020 02:48:33

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:14', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30927400-5a51-478a-8b83-09567cfbd307'	System	09 Aug 2020 02:48:33
User entered 'No (N)'	System	09 Aug 2020 02:48:33

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:25', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30927400-5a51-478a-8b83-09567cfbd307'	System	09 Aug 2020 02:48:33
User entered 'None (1)'	System	09 Aug 2020 02:48:33

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:31', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30927400-5a51-478a-8b83-09567cfbd307' User entered '08 Aug 2020 22:48'	System	09 Aug 2020 02:48:33
	System	09 Aug 2020 02:48:33

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 18:08'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 2'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:06:09', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '95ed4e3e-0a9a-4c00-8421-066ba3b4a184'	System	10 Aug 2020 00:07:05
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		10 Aug 2020 00:07:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:06:31', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '95ed4e3e-0a9a-4c00-8421-066ba3b4a184' User entered 'No (N)'	System	10 Aug 2020 00:07:05
	System	10 Aug 2020 00:07:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:06:35', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '95ed4e3e-0a9a-4c00-8421-066ba3b4a184' User entered 'No (N)'	System	10 Aug 2020 00:07:05
	System	10 Aug 2020 00:07:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:06:53', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '95ed4e3e-0a9a-4c00-8421-066ba3b4a184' User entered 'None (1)'	System	10 Aug 2020 00:07:05
	System	10 Aug 2020 00:07:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:07:01', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '95ed4e3e-0a9a-4c00-8421-066ba3b4a184' User entered '09 Aug 2020 20:07'	System	10 Aug 2020 00:07:05
	System	10 Aug 2020 00:07:05

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 3'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:25', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f265d76b-c85c-4811-b71a-00d659f9cc63'	System	11 Aug 2020 14:20:52
User entered 'None (1)'	System	11 Aug 2020 14:20:52

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:27', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f265d76b-c85c-4811-b71a-00d659f9cc63' User entered 'No (N)'	System	11 Aug 2020 14:20:52
	System	11 Aug 2020 14:20:52

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:30', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f265d76b-c85c-4811-b71a-00d659f9cc63' User entered 'No (N)'	System	11 Aug 2020 14:20:52
	System	11 Aug 2020 14:20:52

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:45', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f265d76b-c85c-4811-b71a-00d659f9cc63' User entered 'None (1)'	System	11 Aug 2020 14:20:52
	System	11 Aug 2020 14:20:52

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:48', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f265d76b-c85c-4811-b71a-00d659f9cc63' User entered '11 Aug 2020 10:20'	System	11 Aug 2020 14:20:52
	System	11 Aug 2020 14:20:52

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 4'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:22:51', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1a71984d-8244-4417-8957-755032ff5220' User entered 'None (1)'	System	12 Aug 2020 12:23:12
	System	12 Aug 2020 12:23:12

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:22:54', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1a71984d-8244-4417-8957-755032ff5220' User entered 'No (N)'	System	12 Aug 2020 12:23:12
	System	12 Aug 2020 12:23:12

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:22:56', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1a71984d-8244-4417-8957-755032ff5220' User entered 'No (N)'	System	12 Aug 2020 12:23:12
	System	12 Aug 2020 12:23:12

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:06', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1a71984d-8244-4417-8957-755032ff5220' User entered 'None (1)'	System	12 Aug 2020 12:23:12
	System	12 Aug 2020 12:23:12

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:09', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1a71984d-8244-4417-8957-755032ff5220' User entered '12 Aug 2020 08:23'	System	12 Aug 2020 12:23:12
	System	12 Aug 2020 12:23:12

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 5'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:14:41', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'df546d4f-f8d3-4893-b5c3-078975ea43f7'	System	13 Aug 2020 12:15:04
User entered 'None (1)'	System	13 Aug 2020 12:15:04

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:14:44', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'df546d4f-f8d3-4893-b5c3-078975ea43f7'	System	13 Aug 2020 12:15:04
User entered 'No (N)'	System	13 Aug 2020 12:15:04

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:14:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'df546d4f-f8d3-4893-b5c3-078975ea43f7' User entered 'No (N)'	System	13 Aug 2020 12:15:04
	System	13 Aug 2020 12:15:04

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:14:58', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'df546d4f-f8d3-4893-b5c3-078975ea43f7'	System	13 Aug 2020 12:15:04
User entered 'None (1)'	System	13 Aug 2020 12:15:04

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:00', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'df546d4f-f8d3-4893-b5c3-078975ea43f7'	System	13 Aug 2020 12:15:04
User entered '13 Aug 2020 08:15'	System	13 Aug 2020 12:15:04

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 6'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:19:50', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30f41b7f-bdf7-429d-91c6-011395200902'	System	13 Aug 2020 22:20:20
User entered 'None (1)'	System	13 Aug 2020 22:20:20

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:02', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30f41b7f-bdf7-429d-91c6-011395200902' User entered 'No (N)'	System	13 Aug 2020 22:20:20
	System	13 Aug 2020 22:20:20

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:06', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30f41b7f-bdf7-429d-91c6-011395200902'	System	13 Aug 2020 22:20:20
User entered 'No (N)'	System	13 Aug 2020 22:20:20

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:13', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30f41b7f-bdf7-429d-91c6-011395200902'	System	13 Aug 2020 22:20:20
User entered 'None (1)'	System	13 Aug 2020 22:20:20

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:17', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '30f41b7f-bdf7-429d-91c6-011395200902' User entered '13 Aug 2020 18:20'	System	13 Aug 2020 22:20:20
	System	13 Aug 2020 22:20:20

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 7'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:42', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0dd78119-abcd-458c-8e9a-1a15ce0ccca5'	System	15 Aug 2020 11:59:53
User entered 'None (1)'	System	15 Aug 2020 11:59:53

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:44', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0dd78119-abcd-458c-8e9a-1a15ce0ccca5'	System	15 Aug 2020 11:59:53
User entered 'No (N)'	System	15 Aug 2020 11:59:53

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:46', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0dd78119-abcd-458c-8e9a-1a15ce0ccca5'	System	15 Aug 2020 11:59:53
User entered 'No (N)'	System	15 Aug 2020 11:59:53

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:48', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0dd78119-abcd-458c-8e9a-1a15ce0ccca5'	System	15 Aug 2020 11:59:53
User entered 'None (1)'	System	15 Aug 2020 11:59:53

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:51', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0dd78119-abcd-458c-8e9a-1a15ce0ccca5' User entered '15 Aug 2020 07:59'	System	15 Aug 2020 11:59:53
	System	15 Aug 2020 11:59:53

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:27', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0499613-24ec-494a-b654-ce1f7e6b3baa' User entered 'None (0)'	System	08 Aug 2020 18:57:01
	System	08 Aug 2020 18:57:01

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:30', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0499613-24ec-494a-b654-ce1f7e6b3baa' User entered 'None (0)'	System	08 Aug 2020 18:57:01
	System	08 Aug 2020 18:57:01

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:33', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0499613-24ec-494a-b654-ce1f7e6b3baa' User entered 'None (0)'	System	08 Aug 2020 18:57:01
	System	08 Aug 2020 18:57:01

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:37', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0499613-24ec-494a-b654-ce1f7e6b3baa' User entered 'None (0)'	System	08 Aug 2020 18:57:01
	System	08 Aug 2020 18:57:01

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:42', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0499613-24ec-494a-b654-ce1f7e6b3baa' User entered 'None (0)'	System	08 Aug 2020 18:57:01
	System	08 Aug 2020 18:57:01

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:45', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0499613-24ec-494a-b654-ce1f7e6b3baa' User entered 'None (0)'	System	08 Aug 2020 18:57:01
	System	08 Aug 2020 18:57:01

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

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)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:51', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0499613-24ec-494a-b654-ce1f7e6b3baa'	System	08 Aug 2020 18:57:01
User entered 'No (N)'	System	08 Aug 2020 18:57:01

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T14:56:59', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0499613-24ec-494a-b654-ce1f7e6b3baa' User entered '08 Aug 2020 14:56'	System	08 Aug 2020 18:57:01
	System	08 Aug 2020 18:57:01

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 14:43'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 17:13'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:36', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '16b8a0cd-2907-4c25-b2d9-b234b305ef10' User entered 'None (0)'	System	09 Aug 2020 02:48:59
	System	09 Aug 2020 02:48:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:39', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '16b8a0cd-2907-4c25-b2d9-b234b305ef10' User entered 'None (0)'	System	09 Aug 2020 02:48:59
	System	09 Aug 2020 02:48:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:43', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '16b8a0cd-2907-4c25-b2d9-b234b305ef10' User entered 'None (0)'	System	09 Aug 2020 02:48:59
	System	09 Aug 2020 02:48:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:48', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '16b8a0cd-2907-4c25-b2d9-b234b305ef10' User entered 'None (0)'	System	09 Aug 2020 02:48:59
	System	09 Aug 2020 02:48:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:50', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '16b8a0cd-2907-4c25-b2d9-b234b305ef10' User entered 'None (0)'	System	09 Aug 2020 02:48:59
	System	09 Aug 2020 02:48:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:53', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '16b8a0cd-2907-4c25-b2d9-b234b305ef10' User entered 'None (0)'	System	09 Aug 2020 02:48:59
	System	09 Aug 2020 02:48:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

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)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:56', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '16b8a0cd-2907-4c25-b2d9-b234b305ef10' User entered 'No (N)'	System	09 Aug 2020 02:48:59
	System	09 Aug 2020 02:48:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-08T22:48:58', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '16b8a0cd-2907-4c25-b2d9-b234b305ef10' User entered '08 Aug 2020 22:48'	System	09 Aug 2020 02:48:59
	System	09 Aug 2020 02:48:59

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '08 Aug 2020 18:08'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 2'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:07:24', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd4931767-aeb1-49f2-80c2-1492d28ad60a' User entered 'None (0)'	System	10 Aug 2020 00:08:16
	System	10 Aug 2020 00:08:16

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:07:46', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd4931767-aeb1-49f2-80c2-1492d28ad60a' User entered 'None (0)'	System	10 Aug 2020 00:08:16
	System	10 Aug 2020 00:08:16

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:07:51', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd4931767-aeb1-49f2-80c2-1492d28ad60a' User entered 'None (0)'	System	10 Aug 2020 00:08:16
	System	10 Aug 2020 00:08:16

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:07:54', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd4931767-aeb1-49f2-80c2-1492d28ad60a' User entered 'None (0)'	System	10 Aug 2020 00:08:16
	System	10 Aug 2020 00:08:16

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:07:57', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd4931767-aeb1-49f2-80c2-1492d28ad60a' User entered 'None (0)'	System	10 Aug 2020 00:08:16
	System	10 Aug 2020 00:08:16

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:08:00', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd4931767-aeb1-49f2-80c2-1492d28ad60a' User entered 'None (0)'	System	10 Aug 2020 00:08:16
	System	10 Aug 2020 00:08:16

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

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)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:08:05', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd4931767-aeb1-49f2-80c2-1492d28ad60a' User entered 'No (N)'	System	10 Aug 2020 00:08:16
	System	10 Aug 2020 00:08:16

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-09T20:08:15', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd4931767-aeb1-49f2-80c2-1492d28ad60a' User entered '09 Aug 2020 20:08'	System	10 Aug 2020 00:08:16
	System	10 Aug 2020 00:08:16

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 3'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:52', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f4119ec0-b54b-49e7-bf0c-ffe145a8fff3' User entered 'None (0)'	System	11 Aug 2020 14:21:15
	System	11 Aug 2020 14:21:15

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:20:54', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f4119ec0-b54b-49e7-bf0c-ffe145a8fff3' User entered 'None (0)'	System	11 Aug 2020 14:21:15
	System	11 Aug 2020 14:21:15

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:21:00', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f4119ec0-b54b-49e7-bf0c-ffe145a8fff3' User entered 'None (0)'	System	11 Aug 2020 14:21:15
	System	11 Aug 2020 14:21:15

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:21:02', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f4119ec0-b54b-49e7-bf0c-ffe145a8fff3' User entered 'None (0)'	System	11 Aug 2020 14:21:15
	System	11 Aug 2020 14:21:15

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:21:04', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f4119ec0-b54b-49e7-bf0c-ffe145a8fff3' User entered 'None (0)'	System	11 Aug 2020 14:21:15
	System	11 Aug 2020 14:21:15

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:21:06', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f4119ec0-b54b-49e7-bf0c-ffe145a8fff3' User entered 'None (0)'	System	11 Aug 2020 14:21:15
	System	11 Aug 2020 14:21:15

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

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)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:21:11', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f4119ec0-b54b-49e7-bf0c-ffe145a8fff3'	System	11 Aug 2020 14:21:15
User entered 'No (N)'	System	11 Aug 2020 14:21:15

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-11T10:21:13', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f4119ec0-b54b-49e7-bf0c-ffe145a8fff3'	System	11 Aug 2020 14:21:15
User entered '11 Aug 2020 10:21'	System	11 Aug 2020 14:21:15

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 4'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:14', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6c312d56-f268-475f-97a3-2ea0fdc47d50' User entered 'None (0)'	System	12 Aug 2020 12:23:33
	System	12 Aug 2020 12:23:33

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:16', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6c312d56-f268-475f-97a3-2ea0fdc47d50' User entered 'None (0)'	System	12 Aug 2020 12:23:33
	System	12 Aug 2020 12:23:33

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:18', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6c312d56-f268-475f-97a3-2ea0fdc47d50' User entered 'None (0)'	System	12 Aug 2020 12:23:33
	System	12 Aug 2020 12:23:33

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:20', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6c312d56-f268-475f-97a3-2ea0fdc47d50' User entered 'None (0)'	System	12 Aug 2020 12:23:33
	System	12 Aug 2020 12:23:33

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:23', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6c312d56-f268-475f-97a3-2ea0fdc47d50' User entered 'None (0)'	System	12 Aug 2020 12:23:33
	System	12 Aug 2020 12:23:33

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:25', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6c312d56-f268-475f-97a3-2ea0fdc47d50' User entered 'None (0)'	System	12 Aug 2020 12:23:33
	System	12 Aug 2020 12:23:33

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

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)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:27', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6c312d56-f268-475f-97a3-2ea0fdc47d50'	System	12 Aug 2020 12:23:33
User entered 'No (N)'	System	12 Aug 2020 12:23:33

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-12T08:23:30', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6c312d56-f268-475f-97a3-2ea0fdc47d50' User entered '12 Aug 2020 08:23'	System	12 Aug 2020 12:23:33
	System	12 Aug 2020 12:23:33

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 5'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:05', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf133a4c-21bb-4e1f-aeb8-99be0b8a52aa' User entered 'None (0)'	System	13 Aug 2020 12:15:35
	System	13 Aug 2020 12:15:35

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:07', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf133a4c-21bb-4e1f-aeb8-99be0b8a52aa' User entered 'None (0)'	System	13 Aug 2020 12:15:35
	System	13 Aug 2020 12:15:35

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:10', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf133a4c-21bb-4e1f-aeb8-99be0b8a52aa' User entered 'None (0)'	System	13 Aug 2020 12:15:35
	System	13 Aug 2020 12:15:35

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:12', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf133a4c-21bb-4e1f-aeb8-99be0b8a52aa' User entered 'None (0)'	System	13 Aug 2020 12:15:35
	System	13 Aug 2020 12:15:35

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:15', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf133a4c-21bb-4e1f-aeb8-99be0b8a52aa' User entered 'None (0)'	System	13 Aug 2020 12:15:35
	System	13 Aug 2020 12:15:35

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:17', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf133a4c-21bb-4e1f-aeb8-99be0b8a52aa' User entered 'None (0)'	System	13 Aug 2020 12:15:35
	System	13 Aug 2020 12:15:35

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

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)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:30', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf133a4c-21bb-4e1f-aeb8-99be0b8a52aa'	System	13 Aug 2020 12:15:35
User entered 'No (N)'	System	13 Aug 2020 12:15:35

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T08:15:32', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf133a4c-21bb-4e1f-aeb8-99be0b8a52aa' User entered '13 Aug 2020 08:15'	System	13 Aug 2020 12:15:35
	System	13 Aug 2020 12:15:35

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 6'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:21', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '39e86dd8-4038-4d5e-b685-f5d94e81169e' User entered 'None (0)'	System	13 Aug 2020 22:21:08
	System	13 Aug 2020 22:21:08

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:25', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '39e86dd8-4038-4d5e-b685-f5d94e81169e' User entered 'None (0)'	System	13 Aug 2020 22:21:08
	System	13 Aug 2020 22:21:08

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:27', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '39e86dd8-4038-4d5e-b685-f5d94e81169e' User entered 'None (0)'	System	13 Aug 2020 22:21:08
	System	13 Aug 2020 22:21:08

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:31', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '39e86dd8-4038-4d5e-b685-f5d94e81169e' User entered 'None (0)'	System	13 Aug 2020 22:21:08
	System	13 Aug 2020 22:21:08

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:36', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '39e86dd8-4038-4d5e-b685-f5d94e81169e' User entered 'None (0)'	System	13 Aug 2020 22:21:08
	System	13 Aug 2020 22:21:08

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:38', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '39e86dd8-4038-4d5e-b685-f5d94e81169e' User entered 'None (0)'	System	13 Aug 2020 22:21:08
	System	13 Aug 2020 22:21:08

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

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)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:20:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '39e86dd8-4038-4d5e-b685-f5d94e81169e' User entered 'Yes (Y)'	System	13 Aug 2020 22:21:08
	System	13 Aug 2020 22:21:08

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-13T18:21:02', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '39e86dd8-4038-4d5e-b685-f5d94e81169e' User entered '13 Aug 2020 18:21'	System	13 Aug 2020 22:21:08
	System	13 Aug 2020 22:21:08

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 7'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:54', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '27362313-3412-4114-924d-ba71bf0a9ab9' User entered 'None (0)'	System	15 Aug 2020 12:00:19
	System	15 Aug 2020 12:00:19

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:56', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '27362313-3412-4114-924d-ba71bf0a9ab9' User entered 'None (0)'	System	15 Aug 2020 12:00:19
	System	15 Aug 2020 12:00:19

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T07:59:58', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '27362313-3412-4114-924d-ba71bf0a9ab9' User entered 'None (0)'	System	15 Aug 2020 12:00:19
	System	15 Aug 2020 12:00:19

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T08:00:00', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '27362313-3412-4114-924d-ba71bf0a9ab9' User entered 'None (0)'	System	15 Aug 2020 12:00:19
	System	15 Aug 2020 12:00:19

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T08:00:02', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '27362313-3412-4114-924d-ba71bf0a9ab9' User entered 'None (0)'	System	15 Aug 2020 12:00:19
	System	15 Aug 2020 12:00:19

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T08:00:03', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '27362313-3412-4114-924d-ba71bf0a9ab9' User entered 'None (0)'	System	15 Aug 2020 12:00:19
	System	15 Aug 2020 12:00:19

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

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)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T08:00:13', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '27362313-3412-4114-924d-ba71bf0a9ab9'	System	15 Aug 2020 12:00:19
User entered 'No (N)'	System	15 Aug 2020 12:00:19

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-08-15T08:00:15', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '27362313-3412-4114-924d-ba71bf0a9ab9' User entered '15 Aug 2020 08:00'	System	15 Aug 2020 12:00:19
	System	15 Aug 2020 12:00:19

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 18:41:51

US3402300

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 16:10:52

US3402300

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '15 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 16:10:52

US3402300

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 16:10:52

US3402300

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 16:10:52

US3402300

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 16:11:04

US3402300

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User entered 'I'	System	16 Aug 2020 16:11:04

US3402300

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	02 Sep 2020 11:02:37

US3402300

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '22 Aug 2020'	(b) (4)	
	Traci Hull (b) (4)	02 Sep 2020 11:02:37
	(b) (4)	

US3402300

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	02 Sep 2020 11:02:37

US3402300

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	02 Sep 2020 11:02:37
	(b) (4)	

US3402300

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Sep 2020 11:02:42

US3402300

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:03:11
User entered 'I'	System	02 Sep 2020 11:02:42

US3402300

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:41:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	02 Sep 2020 11:03:03

US3402300

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:41:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '29 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Sep 2020 11:03:03

US3402300

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:41:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	02 Sep 2020 11:03:03

US3402300

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:41:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Traci Hull (b) (4)	02 Sep 2020 11:03:03

US3402300

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:41:47
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	02 Sep 2020 11:03:07

US3402300

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:41:47
User entered 'I'	System	02 Sep 2020 11:03:07

US3402300

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:20:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '9 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:20:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Clinic (Clinic)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:20:14
	(b) (4)	

US3402300

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'VISIT2'	System	09 Sep 2020 17:20:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User accepted default value 'Pre-Dose (PREDOSE)'	Tammy Kohn (b) (4)	09 Sep 2020 17:21:19
	(b) (4)	

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '9 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '09:13'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered '9 Sep 2020 09:13'	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '97.8' F	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '74'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'bpm'	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '14'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'breaths/min'	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '113'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19
	(b) (4)	

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'mmHg'	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '75'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'mmHg'	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User accepted default value 'Post-Dose (POSTDOSE)'	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:21:19

US3402300

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:50

US3402300

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '9 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:21:50

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:22:17

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '9 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:22:17

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Urine (URINE)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:22:17

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Negative (NEGATIVE)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:22:17

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User closed query 'Per CDM, please provide response to current question, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 05:06:55
Query 'Per CDM, please provide response to current question, otherwise clarify.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 11:27:01
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Oct 2020 11:26:58
User opened query 'Per CDM, please provide response to current question, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 10:38:00
User entered empty.	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 17:22:17

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:22:17

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:22:17

US3402300

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:22:17

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Tammy Kohn (b) (4)	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Herpes simplex'	Tammy Kohn (b) (4)	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:25:35

US3402300

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:25:58

US3402300

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '9 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:25:58

US3402300

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '09:33'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:25:58

US3402300

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered '9 Sep 2020 09:33'	System	09 Sep 2020 17:25:58

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:35:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '9 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '09:31'	(b) (4) Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered '9 Sep 2020 09:31'	System	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tammy Kohn (b) (4) (b) (4)	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered empty.	System	09 Sep 2020 17:26:14

US3402300

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	09 Sep 2020 17:26:48

US3402300

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'I'	System	09 Sep 2020 17:26:48

US3402300

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	17 Sep 2020 12:16:47

US3402300

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '17 Sep 2020'	Traci Hull (b) (4)	17 Sep 2020 12:16:47

US3402300

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	17 Sep 2020 12:16:47

US3402300

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	17 Sep 2020 12:16:47
	(b) (4)	

US3402300

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4)	17 Sep 2020 12:17:45
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'I'	System	17 Sep 2020 12:17:45

US3402300

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	25 Sep 2020 14:32:27

US3402300

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '25 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	25 Sep 2020 14:32:27

US3402300

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	25 Sep 2020 14:32:27

US3402300

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4) Tammy Kohn (b) (4)	25 Sep 2020 14:32:27
	(b) (4)	

US3402300

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	25 Sep 2020 14:32:31

US3402300

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'I'	System	25 Sep 2020 14:32:31

US3402300

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:29:27

US3402300

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '2 Oct 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	08 Oct 2020 15:29:27

US3402300

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:29:27

US3402300

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	08 Oct 2020 15:29:27
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Oct 2020 15:29:50

US3402300

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'I'	System	08 Oct 2020 15:29:50

US3402300

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:30:08

US3402300

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Oct 2020'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:30:08

US3402300

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	08 Oct 2020 15:30:08

US3402300

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'VISIT3'	System	08 Oct 2020 15:30:08

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Oct 2020'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '10:36'	(b) (4)	08 Oct 2020 15:30:43
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered '8 Oct 2020 10:36'	System	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '36.6' C	Traci Hull (b) (4)	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	08 Oct 2020 15:30:43
	(b) (4)	

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '78'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'bpm'	System	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '14'	Traci Hull (b) (4)	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'breaths/min'	System	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '114'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'mmHg'	System	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '64'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'mmHg'	System	08 Oct 2020 15:30:43

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39

US3402300

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39

US3402300

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'No (N)'	(b) (4)	08 Oct 2020 15:30:49
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered empty.	Traci Hull (b) (4)	08 Oct 2020 15:30:49

US3402300

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:31:02

US3402300

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '8 Oct 2020'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:31:02

US3402300

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered '10:42'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:31:02

US3402300

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered '8 Oct 2020 10:42'	System	08 Oct 2020 15:31:02

US3402300

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:50:20
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	08 Oct 2020 15:31:07

US3402300

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'I'	System	08 Oct 2020 15:31:07

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 64'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 71'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-10-16T19:39:35', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '5cef8781-387c-4990-9b74-9cad1ceb6efd' User entered 'No (N)'	System	16 Oct 2020 23:39:49
	System	16 Oct 2020 23:39:49

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-10-16T19:39:38', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '5cef8781-387c-4990-9b74-9cad1ceb6efd'	System	16 Oct 2020 23:39:49
User entered 'No (N)'	System	16 Oct 2020 23:39:49

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-10-16T19:39:45', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '5cef8781-387c-4990-9b74-9cad1ceb6efd' User entered '16 Oct 2020 19:39:45'	System	16 Oct 2020 23:39:49
	System	16 Oct 2020 23:39:49

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 78'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-10-22T08:23:58', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '425f20d4-de9a-4c9a-bb20-7aaad4843df5'	System	22 Oct 2020 12:24:10
User entered 'No (N)'	System	22 Oct 2020 12:24:10

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-10-22T08:24:03', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '425f20d4-de9a-4c9a-bb20-7aaad4843df5'	System	22 Oct 2020 12:24:10
User entered 'No (N)'	System	22 Oct 2020 12:24:10

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-10-22T08:24:07', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '425f20d4-de9a-4c9a-bb20-7aaad4843df5' User entered '22 Oct 2020 08:24:07'	System	22 Oct 2020 12:24:10
	System	22 Oct 2020 12:24:10

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 92'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-08T17:59:25', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '345f37a0-1aa8-48a8-b7c5-97c68ce7b71e' User entered 'No (N)'	System	08 Nov 2020 22:59:35
	System	08 Nov 2020 22:59:35

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-08T17:59:29', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '345f37a0-1aa8-48a8-b7c5-97c68ce7b71e' User entered 'No (N)'	System	08 Nov 2020 22:59:35
	System	08 Nov 2020 22:59:35

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-08T17:59:32', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '345f37a0-1aa8-48a8-b7c5-97c68ce7b71e' User entered '08 Nov 2020 17:59:32'	System	08 Nov 2020 22:59:35
	System	08 Nov 2020 22:59:35

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 99'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-12T07:36:51', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '70b9fbbc-38a9-4e6e-8451-94c9902a56dc' User entered 'No (N)'	System	12 Nov 2020 12:37:02
	System	12 Nov 2020 12:37:02

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-12T07:36:56', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '70b9fbbc-38a9-4e6e-8451-94c9902a56dc' User entered 'No (N)'	System	12 Nov 2020 12:37:02
	System	12 Nov 2020 12:37:02

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-12T07:36:58', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '70b9fbbc-38a9-4e6e-8451-94c9902a56dc' User entered '12 Nov 2020 07:36:58'	System	12 Nov 2020 12:37:02
	System	12 Nov 2020 12:37:02

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:22:15
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17
Data entry locked.	System	08 Aug 2020 18:41:51
User entered 'Day 106'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 18:41:51

US3402300

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:41:17
Data entry locked.	System	08 Aug 2020 18:41:51
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 18:41:51

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-20T18:06:32', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '3391629a-7fe0-44a4-9f67-f7c039e1130e' User entered 'No (N)'	System	20 Nov 2020 23:07:02
	System	20 Nov 2020 23:07:02

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-20T18:06:52', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '3391629a-7fe0-44a4-9f67-f7c039e1130e' User entered 'No (N)'	System	20 Nov 2020 23:07:02

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-20T18:06:58', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '3391629a-7fe0-44a4-9f67-f7c039e1130e' User entered '20 Nov 2020 18:06:58'	System	20 Nov 2020 23:07:02
	System	20 Nov 2020 23:07:02

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-23T14:53:24', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'ab12087e-7daf-467b-ae0b-6805469cb309' User entered 'No (N)'	System	23 Nov 2020 19:54:40
	System	23 Nov 2020 19:54:40

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-23T14:53:48', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'ab12087e-7daf-467b-ae0b-6805469cb309' User entered 'No (N)'	System	23 Nov 2020 19:54:40
	System	23 Nov 2020 19:54:40

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-11-23T14:54:34', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'ab12087e-7daf-467b-ae0b-6805469cb309' User entered '23 Nov 2020 14:54:34'	System	23 Nov 2020 19:54:40
	System	23 Nov 2020 19:54:40

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-09T12:03:02', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b47e1b30-142d-4363-987f-03667a8ffec4' User entered 'No (N)'	System	09 Dec 2020 17:03:15
	System	09 Dec 2020 17:03:15

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-09T12:03:08', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b47e1b30-142d-4363-987f-03667a8ffec4' User entered 'No (N)'	System	09 Dec 2020 17:03:15
	System	09 Dec 2020 17:03:15

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-09T12:03:11', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b47e1b30-142d-4363-987f-03667a8ffec4' User entered '09 Dec 2020 12:03:11'	System	09 Dec 2020 17:03:15
	System	09 Dec 2020 17:03:15

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-14T07:41:28', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd81fd951-a4bb-4f0d-9872-0e3b03396e0c'	System	14 Dec 2020 12:41:41
User entered 'No (N)'	System	14 Dec 2020 12:41:41

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-14T07:41:34', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd81fd951-a4bb-4f0d-9872-0e3b03396e0c' User entered 'No (N)'	System	14 Dec 2020 12:41:41
	System	14 Dec 2020 12:41:41

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-14T07:41:38', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'd81fd951-a4bb-4f0d-9872-0e3b03396e0c' User entered '14 Dec 2020 07:41:38'	System	14 Dec 2020 12:41:41
	System	14 Dec 2020 12:41:41

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-21T06:48:18', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'a8d24492-4eb1-4656-9e70-03f5a70aa101'	System	21 Dec 2020 11:48:33
User entered 'No (N)'	System	21 Dec 2020 11:48:33

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-21T06:48:26', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'a8d24492-4eb1-4656-9e70-03f5a70aa101'	System	21 Dec 2020 11:48:33
User entered 'No (N)'	System	21 Dec 2020 11:48:33

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-21T06:48:30', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'a8d24492-4eb1-4656-9e70-03f5a70aa101' User entered '21 Dec 2020 06:48:30'	System	21 Dec 2020 11:48:33
	System	21 Dec 2020 11:48:33

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-28T07:56:53', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'ae010f79-c2cc-405d-a89d-8e638c3587b9' User entered 'No (N)'	System	28 Dec 2020 12:57:02
	System	28 Dec 2020 12:57:02

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-28T07:56:57', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'ae010f79-c2cc-405d-a89d-8e638c3587b9' User entered 'No (N)'	System	28 Dec 2020 12:57:02
	System	28 Dec 2020 12:57:02

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2020-12-28T07:56:59', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'ae010f79-c2cc-405d-a89d-8e638c3587b9' User entered '28 Dec 2020 07:56:59'	System	28 Dec 2020 12:57:02
	System	28 Dec 2020 12:57:02

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:18', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered 'Yes (Y)'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:22', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered 'Yes (Y)'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Please 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:27', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:32', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd' User entered 'Yes (Y)'	System	04 Jan 2021 13:19:19
	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd' User entered '0'	System	04 Jan 2021 13:19:19
	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd' User entered '0'	System	04 Jan 2021 13:19:19
	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '1'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '1'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd' User entered '0'	System	04 Jan 2021 13:19:19
	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd' User entered '1'	System	04 Jan 2021 13:19:19
	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd' User entered '0'	System	04 Jan 2021 13:19:19
	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:47', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered '0'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Please 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:52', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:18:59', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd' User entered 'Yes (Y)'	System	04 Jan 2021 13:19:19
	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Please 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:19:02', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd'	System	04 Jan 2021 13:19:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-04T08:19:08', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '1f46eb02-3975-4905-b3f9-c89a78fb61dd' User entered '04 Jan 2021 08:19:08'	System	04 Jan 2021 13:19:19
	System	04 Jan 2021 13:19:19

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-14T17:59:43', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6278d918-8265-41ad-8cfa-cd83ce538ee6'	System	14 Jan 2021 22:59:51
User entered 'No (N)'	System	14 Jan 2021 22:59:51

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-14T17:59:46', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6278d918-8265-41ad-8cfa-cd83ce538ee6'	System	14 Jan 2021 22:59:51
User entered 'No (N)'	System	14 Jan 2021 22:59:51

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-14T17:59:49', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '6278d918-8265-41ad-8cfa-cd83ce538ee6' User entered '14 Jan 2021 17:59:49'	System	14 Jan 2021 22:59:51
	System	14 Jan 2021 22:59:51

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-20T12:12:15', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b90236f2-ef67-4c57-84dd-fd8cbd5ecc75'	System	20 Jan 2021 17:12:27
User entered 'No (N)'	System	20 Jan 2021 17:12:27

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-20T12:12:18', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b90236f2-ef67-4c57-84dd-fd8cbd5ecc75'	System	20 Jan 2021 17:12:27
User entered 'No (N)'	System	20 Jan 2021 17:12:27

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-20T12:12:22', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'b90236f2-ef67-4c57-84dd-fd8cbd5ecc75'	System	20 Jan 2021 17:12:27
User entered '20 Jan 2021 12:12:22'	System	20 Jan 2021 17:12:27

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-27T12:01:29', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '11373a9e-887a-4986-91d2-bb7e2e29dc53'	System	27 Jan 2021 17:05:12
User entered 'No (N)'	System	27 Jan 2021 17:05:12

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-27T12:02:09', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '11373a9e-887a-4986-91d2-bb7e2e29dc53'	System	27 Jan 2021 17:05:12
User entered 'No (N)'	System	27 Jan 2021 17:05:12

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-01-27T12:02:12', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '11373a9e-887a-4986-91d2-bb7e2e29dc53'	System	27 Jan 2021 17:05:12
User entered '27 Jan 2021 12:02:12'	System	27 Jan 2021 17:05:12

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-01T05:30:34', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0ba38612-3405-455f-90fa-cb67e46e303b' User entered 'No (N)'	System	01 Feb 2021 10:30:43
	System	01 Feb 2021 10:30:43

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-01T05:30:38', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0ba38612-3405-455f-90fa-cb67e46e303b' User entered 'No (N)'	System	01 Feb 2021 10:30:43

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-01T05:30:41', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '0ba38612-3405-455f-90fa-cb67e46e303b' User entered '01 Feb 2021 05:30:41'	System	01 Feb 2021 10:30:43
	System	01 Feb 2021 10:30:43

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-15T07:54:03', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '46785e9f-d206-4913-8edb-b6eb02268710'	System	15 Feb 2021 12:54:12
User entered 'No (N)'	System	15 Feb 2021 12:54:12

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-15T07:54:07', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '46785e9f-d206-4913-8edb-b6eb02268710'	System	15 Feb 2021 12:54:12
User entered 'No (N)'	System	15 Feb 2021 12:54:12

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-15T07:54:10', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '46785e9f-d206-4913-8edb-b6eb02268710' User entered '15 Feb 2021 07:54:10'	System	15 Feb 2021 12:54:12
	System	15 Feb 2021 12:54:12

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-22T07:09:14', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf9d3409-5524-4d89-8259-2e3e4f6535f5' User entered 'No (N)'	System	22 Feb 2021 12:09:24
	System	22 Feb 2021 12:09:24

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-22T07:09:18', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf9d3409-5524-4d89-8259-2e3e4f6535f5' User entered 'No (N)'	System	22 Feb 2021 12:09:24
	System	22 Feb 2021 12:09:24

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-02-22T07:09:22', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'cf9d3409-5524-4d89-8259-2e3e4f6535f5' User entered '22 Feb 2021 07:09:22'	System	22 Feb 2021 12:09:24
	System	22 Feb 2021 12:09:24

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-03T14:05:54', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f2f3ac6e-38e3-41a1-8790-f699334c0300' User entered 'No (N)'	System	03 Mar 2021 19:06:06
	System	03 Mar 2021 19:06:06

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-03T14:05:59', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f2f3ac6e-38e3-41a1-8790-f699334c0300'	System	03 Mar 2021 19:06:06
User entered 'No (N)'	System	03 Mar 2021 19:06:06

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-03T14:06:01', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'f2f3ac6e-38e3-41a1-8790-f699334c0300' User entered '03 Mar 2021 14:06:01'	System	03 Mar 2021 19:06:06
	System	03 Mar 2021 19:06:06

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-08T11:51:28', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '63bf5a4a-e725-433b-b3a3-5ff5aa75e57f' User entered 'No (N)'	System	08 Mar 2021 16:51:38
	System	08 Mar 2021 16:51:38

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-08T11:51:31', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '63bf5a4a-e725-433b-b3a3-5ff5aa75e57f'	System	08 Mar 2021 16:51:38
User entered 'No (N)'	System	08 Mar 2021 16:51:38

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-08T11:51:33', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '63bf5a4a-e725-433b-b3a3-5ff5aa75e57f' User entered '08 Mar 2021 11:51:33'	System	08 Mar 2021 16:51:38
	System	08 Mar 2021 16:51:38

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-22T07:23:06', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '764da93f-7236-4cd0-a628-89e2d064bdfc' User entered 'No (N)'	System	22 Mar 2021 11:23:18
	System	22 Mar 2021 11:23:18

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-22T07:23:10', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '764da93f-7236-4cd0-a628-89e2d064bdfc' User entered 'No (N)'	System	22 Mar 2021 11:23:18
	System	22 Mar 2021 11:23:18

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-22T07:23:14', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '764da93f-7236-4cd0-a628-89e2d064bdfc' User entered '22 Mar 2021 07:23:14'	System	22 Mar 2021 11:23:18
	System	22 Mar 2021 11:23:18

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-29T07:18:34', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c7f20703-ab59-4148-b48b-dfb3bfe807e2'	System	29 Mar 2021 11:18:41
User entered 'No (N)'	System	29 Mar 2021 11:18:41

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-29T07:18:36', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c7f20703-ab59-4148-b48b-dfb3bfe807e2'	System	29 Mar 2021 11:18:41
User entered 'No (N)'	System	29 Mar 2021 11:18:41

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-29T07:18:39', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c7f20703-ab59-4148-b48b-dfb3bfe807e2' User entered '29 Mar 2021 07:18:39'	System	29 Mar 2021 11:18:41
	System	29 Mar 2021 11:18:41

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-14T12:00:36', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '37f5a5d7-3586-4e29-ab35-6243c8ce1689' User entered 'No (N)'	System	14 Apr 2021 16:01:53
	System	14 Apr 2021 16:01:53

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-14T12:00:41', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '37f5a5d7-3586-4e29-ab35-6243c8ce1689' User entered 'No (N)'	System	14 Apr 2021 16:01:53
	System	14 Apr 2021 16:01:53

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-14T12:00:44', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '37f5a5d7-3586-4e29-ab35-6243c8ce1689' User entered '14 Apr 2021 12:00:44'	System	14 Apr 2021 16:01:53
	System	14 Apr 2021 16:01:53

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-19T19:05:19', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0f18d17-f6fd-417f-a5e8-3246872ee9b2'	System	19 Apr 2021 23:05:54
User entered 'No (N)'	System	19 Apr 2021 23:05:54

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-19T19:05:23', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0f18d17-f6fd-417f-a5e8-3246872ee9b2'	System	19 Apr 2021 23:05:54
User entered 'No (N)'	System	19 Apr 2021 23:05:54

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-19T19:05:26', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c0f18d17-f6fd-417f-a5e8-3246872ee9b2'	System	19 Apr 2021 23:05:54
User entered '19 Apr 2021 19:05:26'	System	19 Apr 2021 23:05:54

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-26T19:40:30', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c1cc2625-954d-4633-9a2e-e0ddb880a2b5'	System	26 Apr 2021 23:40:50
User entered 'No (N)'	System	26 Apr 2021 23:40:50

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-26T19:40:38', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c1cc2625-954d-4633-9a2e-e0ddb880a2b5'	System	26 Apr 2021 23:40:50
User entered 'No (N)'	System	26 Apr 2021 23:40:50

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-04-26T19:40:43', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'c1cc2625-954d-4633-9a2e-e0ddb880a2b5' User entered '26 Apr 2021 19:40:43'	System	26 Apr 2021 23:40:50
	System	26 Apr 2021 23:40:50

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-05-03T07:35:34', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'e0e24591-6061-4c13-8d7e-1ce9ab9f96ac'	System	03 May 2021 11:35:50
User entered 'No (N)'	System	03 May 2021 11:35:50

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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 (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-05-03T07:35:17', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'e0e24591-6061-4c13-8d7e-1ce9ab9f96ac'	System	03 May 2021 11:35:50
User entered 'No (N)'	System	03 May 2021 11:35:50

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-05-03T07:35:44', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: 'e0e24591-6061-4c13-8d7e-1ce9ab9f96ac'	System	03 May 2021 11:35:50
User entered '03 May 2021 07:35:44'	System	03 May 2021 11:35:50

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:41:17

US3402300

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:41:17
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:41:17

US3402300

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:35:15

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)	26 Apr 2021 06:40:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-03T14:06:10', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '23d8e8f1-c616-42a3-a970-980b0311fbd3'	System	03 Mar 2021 19:06:15
User entered 'No (N)'	System	03 Mar 2021 19:06:15

US3402300

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:35:15

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:40:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (719AB9DF-31AA-4C55-8338-B5DBF00E76D2)', Time: '2021-03-03T14:06:13', User OID: 'PatientReportedOutcome (US3402300)', ODM File OID: '23d8e8f1-c616-42a3-a970-980b0311fbd3' User entered '03 Mar 2021 14:06:13'	System	03 Mar 2021 19:06:15
	System	03 Mar 2021 19:06:15

US3402300

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:32
User entered 'Yes (Y)'	(b) (4)	10 Nov 2020 15:10:47
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:32
User entered '8 Nov 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	10 Nov 2020 15:10:47

US3402300

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	10 Nov 2020 15:10:47

US3402300

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:32
User entered empty.	(b) (4) Traci Hull (b) (4)	10 Nov 2020 15:10:47

US3402300

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:25:32
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	10 Nov 2020 15:10:34

US3402300

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:57:39
User entered 'I'	System	10 Nov 2020 15:10:34

US3402300

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	07 Dec 2020 15:05:33
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '7 Dec 2020'	Traci Hull (b) (4)	07 Dec 2020 15:05:33

US3402300

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	07 Dec 2020 15:05:33

US3402300

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	07 Dec 2020 15:05:33
	(b) (4)	

US3402300

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	07 Dec 2020 15:05:18
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User entered 'I'	System	07 Dec 2020 15:05:18

US3402300

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	Traci Hull (b) (4)	01 Feb 2021 17:08:50

US3402300

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '7 Jan 2021'	Traci Hull (b) (4)	01 Feb 2021 17:08:50

US3402300

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	01 Feb 2021 17:08:50

US3402300

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	01 Feb 2021 17:08:50
	(b) (4)	

US3402300

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	01 Feb 2021 17:08:56
	(b) (4)	

US3402300

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User entered 'I'	System	01 Feb 2021 17:08:56

US3402300

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	Traci Hull (b) (4)	04 Feb 2021 16:04:20

US3402300

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '4 Feb 2021'	Traci Hull (b) (4)	04 Feb 2021 16:04:20

US3402300

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	04 Feb 2021 16:04:20

US3402300

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	04 Feb 2021 16:04:20
	(b) (4)	

US3402300

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	04 Feb 2021 16:04:27
	(b) (4)	

US3402300

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:00
User entered 'I'	System	04 Feb 2021 16:04:27

US3402300

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:07:41
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered '11 Mar 2021'	(b) (4)	11 Mar 2021 17:07:41
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered 'Clinic (Clinic)'	(b) (4)	11 Mar 2021 17:07:41
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User entered 'VISIT4'	System	11 Mar 2021 17:07:41

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 12:59:52
User entered 'No (N)'	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered '11 Mar 2021' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 12:59:52
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered '10:45' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 12:59:52
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User entered '11 Mar 2021 10:45'	System	31 Mar 2021 12:59:52
User entered empty.	System	30 Mar 2021 17:57:55

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 13:00:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 13:00:16
User entered '36.6' C reason for change: Data Entry Error	Tammy Kohn (b) (4)	31 Mar 2021 13:00:16
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 12:59:52
User entered empty.	System	31 Mar 2021 12:59:52
	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	31 Mar 2021 12:59:52
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 17:57:55

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 13:00:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 13:00:16
User entered '78' reason for change: Data Entry Error	Tammy Kohn (b) (4)	31 Mar 2021 13:00:16
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 12:59:52
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User entered 'bpm'	System	31 Mar 2021 13:00:16
User entered empty.	System	30 Mar 2021 17:57:55

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 13:00:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 13:00:16
User entered '16' reason for change: Data Entry Error	Tammy Kohn (b) (4)	31 Mar 2021 13:00:16
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 12:59:52
User entered empty.	System	31 Mar 2021 12:59:52
	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User entered 'breaths/min'	System	31 Mar 2021 13:00:16
User entered empty.	System	30 Mar 2021 17:57:55

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 13:00:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 13:00:16
User entered '121' reason for change: Data Entry Error	Tammy Kohn (b) (4)	31 Mar 2021 13:00:16
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 12:59:52
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User entered 'mmHg'	System	31 Mar 2021 13:00:16
User entered empty.	System	30 Mar 2021 17:57:55

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 13:00:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 13:00:16
User entered '76' reason for change: Data Entry Error	Tammy Kohn (b) (4)	31 Mar 2021 13:00:16
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 12:59:52
User entered empty.	Tammy Kohn (b) (4)	30 Mar 2021 17:57:55
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User entered 'mmHg'	System	31 Mar 2021 13:00:16
User entered empty.	System	30 Mar 2021 17:57:55

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06

US3402300

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06

US3402300

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User closed query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,'Was the physical examination performed?' is NO at this visit but at Participant Decision Visit / OL-D1 ' Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the physical examination data should be entered at both visits per sponsor with same response Yes or No. Please review and update as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 10:42:26
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,'Was the physical examination performed?' is NO at this visit but at Participant Decision Visit / OL-D1 ' Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the physical examination data should be entered at both visits per sponsor with same response Yes or No. Please review and update as appropriate' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 13:18:50
User entered 'Yes (Y)' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 13:18:46
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,'Was the physical examination performed?' is NO at this visit but at Participant Decision Visit / OL-D1 ' Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the physical examination data should be entered at both visits per sponsor with same response Yes or No. Please review and update as appropriate' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:00:23

US3402300

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,'Was the physical examination performed?' is NO at this visit but at OL-D57 ' Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the physical examination data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:00:23
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4)	30 Mar 2021 18:56:59
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,'Was the physical examination performed?' is NO at this visit but at OL-D57 ' Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the physical examination data should be entered at both visits per sponsor. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Tammy Kohn (b) (4)	30 Mar 2021 17:57:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 17:56:20
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,'Was the physical examination performed?' is NO at this visit but at OL-D57 ' Was the physical examination performed?' is YES and data is present. If the visits occurred on the same day, then the physical examination data should be entered at both visits per sponsor. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:26:12
User entered 'No (N)'	Traci Hull (b) (4)	11 Mar 2021 17:08:13

US3402300

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered '11 Mar 2021' reason for change: New Information	Tammy Kohn (b) (4)	01 Apr 2021 13:18:46
User entered empty; reason for change New Information	Traci Hull (b) (4)	30 Mar 2021 18:56:59
User entered '11 Mar 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	30 Mar 2021 17:56:20
User entered empty.	Traci Hull (b) (4)	11 Mar 2021 17:08:13

US3402300

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:08:26

US3402300

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered '11 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	11 Mar 2021 17:08:26
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered '10:24'	(b) (4)	11 Mar 2021 17:08:26
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User entered '11 Mar 2021 10:24'	System	11 Mar 2021 17:08:26

US3402300

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:57
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:08:32
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:54:06
User entered 'I'	System	11 Mar 2021 17:08:32

US3402300

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	06 Apr 2021 12:37:30
	(b) (4)	

US3402300

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered '6 Apr 2021'	Tammy Kohn (b) (4)	06 Apr 2021 12:37:30
	(b) (4)	

US3402300

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	06 Apr 2021 12:37:30

US3402300

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	06 Apr 2021 12:37:30
	(b) (4)	

US3402300

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	06 Apr 2021 12:37:38
	(b) (4)	

US3402300

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 12:37:38

US3402300

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:08:46
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	11 Mar 2021 17:08:46
	(b) (4)	

US3402300

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Clinic (Clinic)'	(b) (4)	11 Mar 2021 17:08:46
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'UNBLND_DECIDE'	System	11 Mar 2021 17:08:46

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '06 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	11 Mar 2021 17:09:29
	(b) (4)	

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '0'	(b) (4)	11 Mar 2021 17:09:29
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:09:29
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Amendment 6 or later (Amendment 6 or later)'	Traci Hull (b) (4)	11 Mar 2021 17:09:29

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	11 Mar 2021 17:09:29
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:09:29

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:09:29

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Not Administered (NA)'	(b) (4)	11 Mar 2021 17:09:29
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:09:29
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered empty.	System	11 Mar 2021 17:09:29

US3402300

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:15

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'I'	System	11 Mar 2021 17:09:29

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered empty.	System	11 Mar 2021 17:11:37
DataPoint set to visible.	System	11 Mar 2021 17:09:29

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered empty.	System	11 Mar 2021 17:11:37
DataPoint set to visible.	System	11 Mar 2021 17:09:29

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User closed query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:53:42
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	31 Mar 2021 12:59:29
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 11Mar2021,However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:25:11
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	11 Mar 2021 17:11:37
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '10:45'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered '11 Mar 2021 10:45'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '36.6' C	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Oral (Oral)'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '78'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'bpm'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '16'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'breaths/min'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '121'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'mmHg'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '73'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'mmHg'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered missing code ND - Not Done.	(b) (4) Traci Hull (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered empty.	System	11 Mar 2021 17:11:37
DataPoint set to visible.	System	11 Mar 2021 17:09:29

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11:55'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered '11 Mar 2021 11:55'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '36.6' C	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Oral (Oral)'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '66'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'bpm'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '16'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'breaths/min'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '115'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'mmHg'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '73'	(b) (4)	11 Mar 2021 17:11:37
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'mmHg'	System	11 Mar 2021 17:11:37

US3402300

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:11:46
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	11 Mar 2021 17:11:46
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:11:55
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	11 Mar 2021 17:11:55
	(b) (4)	

US3402300

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Urine (URINE)'	(b) (4)	11 Mar 2021 17:11:55
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Negative (NEGATIVE)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Mar 2021 17:11:55

US3402300

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'No (N)'	(b) (4)	11 Mar 2021 17:11:55
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4)	11 Mar 2021 17:11:55
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4)	11 Mar 2021 17:11:55
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered empty.	System	11 Mar 2021 17:11:55

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:12:14
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4)	11 Mar 2021 17:12:14
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	Traci Hull (b) (4)	11 Mar 2021 17:12:14

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'mRNA-1273'	System	11 Mar 2021 17:12:14
DataPoint set to visible.	System	11 Mar 2021 17:09:29

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	11 Mar 2021 17:12:14
	(b) (4)	

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11:23'	(b) (4)	11 Mar 2021 17:12:14
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered '11 Mar 2021 11:23'	System	11 Mar 2021 17:12:14

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Left Arm (LEFT ARM)'	Traci Hull (b) (4)	11 Mar 2021 17:12:14

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'ONCE'	System	11 Mar 2021 17:12:14

US3402300

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:15

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'INTRAMUSCULAR'	System	11 Mar 2021 17:12:14

US3402300

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:09:40
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	11 Mar 2021 17:09:40
	(b) (4)	

US3402300

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '10:24'	(b) (4)	11 Mar 2021 17:09:40
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered '11 Mar 2021 10:24'	System	11 Mar 2021 17:09:40

US3402300

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Mar 2021 17:09:50

US3402300

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '11 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	11 Mar 2021 17:09:50
	(b) (4)	

US3402300

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:15

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '10:21'	(b) (4)	11 Mar 2021 17:09:50
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:15

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered '11 Mar 2021 10:21'	System	11 Mar 2021 17:09:50

US3402300

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

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4)	11 Mar 2021 17:09:54
	Traci Hull (b) (4)	
	(b) (4)	

US3402300

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

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:30
User entered 'I'	System	11 Mar 2021 17:09:54

US3402300

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Mar 2021 16:57:18

US3402300

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered '18 Mar 2021'	(b) (4) Traci Hull (b) (4) (b) (4)	18 Mar 2021 16:57:18

US3402300

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Traci Hull (b) (4)	18 Mar 2021 16:57:18

US3402300

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:15

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered empty.	(b) (4) Traci Hull (b) (4)	18 Mar 2021 16:57:18

US3402300

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:04
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	18 Mar 2021 16:57:23

US3402300

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:04
User entered 'I'	System	18 Mar 2021 16:57:23

US3402300

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:15

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:48:04
User entered '1'	System	18 Mar 2021 16:57:23
DataPoint set to visible.	System	18 Mar 2021 16:57:23

US3402300

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	13 Apr 2021 15:48:28
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered '13 Apr 2021'	Tammy Kohn (b) (4)	13 Apr 2021 15:48:28
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	13 Apr 2021 15:48:28
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:15

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	13 Apr 2021 15:48:28

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:48:38

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:48:38

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:48:38

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:48:38

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:38
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:48:38

US3402300

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	13 Apr 2021 15:48:44
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	13 Apr 2021 15:48:44
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	13 Apr 2021 15:48:59
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered '13 Apr 2021'	Tammy Kohn (b) (4)	13 Apr 2021 15:48:59
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
	(b) (4)	
User entered '09:32'	Tammy Kohn (b) (4)	13 Apr 2021 15:48:59
	(b) (4)	

US3402300

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 09:32'	System	13 Apr 2021 15:48:59

US3402300

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:35:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:00
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'SUBJECT WAS CONTACTED WAS TESTED OUTSIDE THE OFFICE FOR COVID -19 WHICH WAS POSITIVE. SUBJECT REFUSED TO COME IN FOR AN ILLNESS VISIT' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 22:20:55
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	06 Apr 2021 12:40:15
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 13:41:57
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:44:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:17:50

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:42
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 16:21:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 16:21:17
	(b) (4)	
Data point term sent to Coder	System	16 Aug 2020 16:20:15
User entered 'HERPES SIMPLEX'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:44
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User closed query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:02:10
Query 'Per CDM: Response is required. Please provide.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	15 Oct 2020 21:11:00
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	15 Oct 2020 21:10:52
	(b) (4)	
User opened query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 12:36:11
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:08:07

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:50
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 09:19:32
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	30 Nov 2020 19:34:58
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	30 Nov 2020 19:34:49
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 09:15:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '25 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	30 Nov 2020 19:34:49
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Aug 2020 16:19:15

US3402300

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:04:16
	(b) (4)	
User closed query 'Per source this is listed as Grade 2 / Moderate. Please clarify and update accordingly. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:55:58
Query 'Per source this is listed as Grade 2 / Moderate. Please clarify and update accordingly. Thank you. ' answered with 'UPDATED' (Site from CRA).	Tammy Kohn (b) (4)	12 Apr 2021 16:54:14
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	12 Apr 2021 16:54:09
	(b) (4)	
Signature has been broken.	Tammy Kohn (b) (4)	12 Apr 2021 16:54:09
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	12 Apr 2021 16:54:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User opened query 'Per source this is listed as Grade 2 / Moderate. Please clarify and update accordingly. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:29:55
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:11
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Aug 2020 16:19:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Aug 2020 16:19:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Aug 2020 16:19:46
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Aug 2020 16:19:15
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:15
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Aug 2020 16:19:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Aug 2020 16:19:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Aug 2020 16:19:46
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Aug 2020 16:19:15
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 20:58:36
	(b) (4)	
Query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' canceled (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:36:42
User opened query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:36:13
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Aug 2020 16:19:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Aug 2020 16:19:46
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Aug 2020 16:19:46
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Aug 2020 16:19:15
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	30 Nov 2020 19:34:49
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:07
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:44:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:19:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 03:08:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:08:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 03:08:09
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:08:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:15

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 03:08:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:01:00
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:35
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:20
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	16 Aug 2020 16:30:31
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 12:55:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:11
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Aug 2020 23:18:18
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Aug 2020 23:18:18
	(b) (4)	
Data point term sent to Coder	System	16 Aug 2020 16:31:20
User entered 'VALTREX (VALCYCLOVIR)'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered 'HERPES SIMPLEX'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered '500'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:21
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:26
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:29
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:31
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	15 Jan 2021 10:31:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	14 Jan 2021 14:29:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Jan 2021 14:29:05
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:46:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered '28 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	14 Jan 2021 14:29:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:31:10

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:37
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 16:31:10

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 16:31:10

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 16:31:10

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Aug 2020 16:31:10

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:43
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 14:23:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 14:22:33
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4)	17 Nov 2020 14:21:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:53:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:53:51
Data point term sent to Coder User entered 'IBUPROFEN'	System Tammy Kohn (b) (4)	02 Oct 2020 20:53:12 02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'No (N)'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, legs, generalized, injection site pain etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 06:28:49
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, legs, generalized, injection site pain etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'DATA UPDATED. NO AE TO REPORT AS THIS WAS WITHIN THE 7 DAYS OF THE INJECTION' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	17 Nov 2020 14:22:51
User entered 'PAIN AT INJECTION SITE' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Nov 2020 14:21:54
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, legs, generalized, injection site pain etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 07:59:16
User entered 'PAIN'	Tammy Kohn (b) (4) (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:28:17
User entered '200' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Nov 2020 16:10:24
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	17 Nov 2020 14:23:30
User entered '400' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Nov 2020 14:23:22
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 07:59:34
User entered '325'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'mg (mg)'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:52
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered empty.	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'every month (QM)'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered empty.	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:59
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered empty.	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
	(b) (4), (b) (6)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered '09 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	02 Oct 2020 20:52:44
	(b) (4)	
User entered '7 Aug 2020'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15
	(b) (4)	

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:01
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered '0'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:04
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered '9 Aug 2020'	Tammy Kohn (b) (4)	02 Oct 2020 20:52:15
	(b) (4)	

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:05
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 14:55:36
Query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' answered with 'NO AE OR SAE AS THIS IS WITHIN THE 7 DAYS AFTER INJECTION' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	07 Jan 2021 21:32:58
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = No. However, this is one of the protocol identified Solicited Adverse Event that fits within reporting timeframe and entry in the diary was noted. Please review if the response in this field should reflect Solicited AE. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:22:58
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
User entered '1'	System	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
User entered '1'	System	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:25
User entered '802 (802)'	System	02 Oct 2020 20:52:15

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:08
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Oct 2020 23:21:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:21:13
Data point term sent to Coder	System	08 Oct 2020 16:03:23
User entered 'TETANUS VACCINE'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:09
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:11
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'TETANUS PREVENTION'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered '0.5'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'mL (mL)'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:15
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered empty.	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'once (ONCE)'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered empty.	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered empty.	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered '25 Sep 2020'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:23
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered '0'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:24
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'No (N)'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:26
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered '25 Sep 2020'	Traci Hull (b) (4)	08 Oct 2020 16:02:41
	(b) (4)	

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:55:27
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:30:48
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
User entered 'No (N)'	Traci Hull (b) (4)	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
User entered empty.	System	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
User entered empty.	System	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:52:28
User entered empty.	System	08 Oct 2020 16:02:41

US3402300

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:35:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:54:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:34:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:36:48
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	04 Sep 2020 15:23:17
	(b) (4)	

US3402300

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:15

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:53:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:28:26
User entered '9 Sep 2020'	Jennifer Molstead (b) (4) (b) (4)	05 Oct 2020 19:31:55

US3402300

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:15

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:53:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:28:26
User closed query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:09:30
Query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	23 Nov 2020 20:58:54
User opened query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:37:05
User entered 'AE (specify) (ADVERSE EVENT)'	Jennifer Molstead (b) (4)	05 Oct 2020 19:31:55

US3402300

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:59:26
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 23:06:27
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:53:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:28:26
User closed query 'Per CDM: Thank you for entering the corresponding AE #; however, the additional text of 'Subject developed herpes simplex' is unnecessary and should be removed. We only need AE #1 recorded.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:09:32
Query 'Per CDM: Thank you for entering the corresponding AE #; however, the additional text of 'Subject developed herpes simplex' is unnecessary and should be removed. We only need AE #1 recorded.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	23 Nov 2020 20:59:13
User entered 'AE #1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 20:59:08
User opened query 'Per CDM: Thank you for entering the corresponding AE #; however, the additional text of 'Subject developed herpes simplex' is unnecessary and should be removed. We only need AE #1 recorded.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:44:22
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 17:44:22
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4)	18 Nov 2020 16:11:54
User entered 'SUBJECT DEVELOPED HERPES SIMPLEX - AE #1' reason for change: Per Query Resolution	Traci Hull (b) (4)	18 Nov 2020 16:11:47
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:03:00
User entered 'Subject Developed Herpes Simplex'	Jennifer Molstead (b) (4)	05 Oct 2020 19:31:55