

US3742395 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3742395

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Participant ID

US3742395

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

US3742395

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Apr 2021 21:48:45

Generated On: 12 Aug 2021 13:21:23

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	MULATO
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:52:12

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

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 17:52:12

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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 17:52:12

Generated On: 12 Aug 2021 13:21:23

Condition	HUMAN IMMUNODEFICIENCY VIRUS (HIV)
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Start Year (derived)	1988
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 17:52:12

Generated On: 12 Aug 2021 13:21:23

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Condition	ALLERGY TO CONTRAST DYE
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Condition	DEEP VEIN THROMBOSIS
Start date (dd MMM yyyy)	UN FEB 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2019
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	FEB 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:23 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:23
Height (<i>xxx.x</i>)	73.0 in
Weight (<i>xxx.x</i>)	214.5 lb
BMI (<i>xxx.x</i>)	28.35904 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 17:52:12

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:52:12

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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 17:52:12

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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)	False
Other	True
Specify	ZIP CODE (b) (6)

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

What was the date of randomization? (dd MMM yyyy) 17 SEP 2020

What was the participant's randomization number? 114499

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 17:52:12

Generated On: 12 Aug 2021 13:21:23

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 17:52:12

Generated On: 12 Aug 2021 13:21:23

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)	17 SEP 2020
Time of assessment (00:00-23:59)	09:23 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:23
Temperature (xxx.x)	097.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	062 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	072 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 17:52:12

Generated On: 12 Aug 2021 13:21:23

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)	17 SEP 2020
Time of assessment (00:00-23:59)	11:01 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:01
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	079 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 17:52:12

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 10:30 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 10:30

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 17:52:12

Generated On: 12 Aug 2021 13:21:23

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

Collection date (dd MMM yyyy)	17 SEP 2020
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Collection time (00:00-23:59)	09:39 (24 HR)
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Collection date and time (derived)	17 SEP 2020 09:39
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:32	17 SEP 2020 09:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

17 SEP 2020 11:01

PC Open Date & Time

17 SEP 2020 10:50

PC Close Date & Time

17 SEP 2020 13:20

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp	17 SEP 2020 15:13
PC Open Date & Time	17 SEP 2020 14:15
PC Close Date & Time	18 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 21:05

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 19:13

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 21:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

21 SEP 2020 20:11

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 21:10

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 20:15

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 11:02

PC Open Date & Time

17 SEP 2020 10:50

PC Close Date & Time

17 SEP 2020 13:20

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

17 SEP 2020 15:13

PC Open Date & Time

17 SEP 2020 14:15

PC Close Date & Time

18 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

18 SEP 2020 21:06

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

19 SEP 2020 19:13

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

20 SEP 2020 21:59

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

21 SEP 2020 20:11

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

22 SEP 2020 21:11

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

23 SEP 2020 20:15

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 11:03
PC Open Date & Time	17 SEP 2020 10:50
PC Close Date & Time	17 SEP 2020 13:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

No ☐

Yes ☒

PC Time stamp	17 SEP 2020 15:14
PC Open Date & Time	17 SEP 2020 14:15
PC Close Date & Time	18 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

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)

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 21:06
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

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 ☒

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 19:14
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

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 ☒

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 22:00
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 20:11
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

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 ☒

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 21:11
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

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 ☒

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 20:15
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3742395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

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)	15 OCT 2020
Time of assessment (00:00-23:59)	09:14 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 09:14
Temperature (xxx.x)	097.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	080 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

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	

US3742395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3742395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

09:08 (24 HR)

Collection date and time (derived)

15 OCT 2020 09:08

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:17	15 OCT 2020 09:17
Nasopharyngeal Swab 2	No		

US3742395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:52:12

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:52:26

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:52:26

Generated On: 12 Aug 2021 13:21:23

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) _____

US3742395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:52:26

Generated On: 12 Aug 2021 13:21:23

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.

US3742395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

08:51 (24 HR)

Collection date and time (derived)

12 NOV 2020 08:51

US3742395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:52:13

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	17 NOV 2020 09:05:30
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 10:51:06
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 10:01:38
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 11:24:24
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 DEC 2020 07:27:35
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 13:43:31
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

26 DEC 2020 07:24:27

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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	02 JAN 2021 18:11:30
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 12:22:20
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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	16 JAN 2021 00:03:52
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 11:40:23

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

30 JAN 2021 06:10:49

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 11:43:51
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 08:26:36

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

20 FEB 2021 06:16:52

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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	27 FEB 2021 08:45:30
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

06 MAR 2021 09:31:52

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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	13 MAR 2021 08:18:29
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 10:23:04

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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	27 MAR 2021 00:23:22
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 APR 2021 08:14:22

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

10 APR 2021 11:46:15

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

17 APR 2021 07:29:34

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 10:06:22

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 09:37:24
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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°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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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°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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	04 DEC 2021 00:01
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Patient Cloud Close Date & Time	08 DEC 2021 23:59
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US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 <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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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="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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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 ☐

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3742395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:21:23

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		06 MAR 2021 09:32:07

US3742395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:48:14

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:48:14

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 22:27:51

Generated On: 12 Aug 2021 13:21:23

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

Visit date (dd MMM yyyy)	15 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 22:27:51

Generated On: 12 Aug 2021 13:21:23

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) _____

US3742395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 22:27:51

Generated On: 12 Aug 2021 13:21:23

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.

US3742395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 22:27:51

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 APR 2021

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

15 APR 2021 08:40

US3742395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 22:27:51

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742395

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:21:23

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"/>

US3742395

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:21:23

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742395

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

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

Visit date (dd MMM yyyy)	20 JAN 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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US3742395

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:49:54

Generated On: 12 Aug 2021 13:21:23

Date of updated informed consent (<i>dd MMM yyyy</i>)	20 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>)	20 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3742395

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

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

US3742395

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

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)	20 JAN 2021
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 09:07
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	065 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	066 mmHg
Diastolic Blood Pressure units	MMHG

US3742395

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

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)	20 JAN 2021
Time of assessment (00:00-23:59)	09:47 (24 HR)
Vital Signs Date and Time (derived)	20 JAN 2021 09:47
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	079 mmHg
Diastolic Blood Pressure units	MMHG

US3742395

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 JAN 2021

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

US3742395

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

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) 20 JAN 2021

What was the treatment time? (00:00-23:59) 09:16 (24 HR)

Treatment Date and Time (derived) 20 JAN 2021 09:16

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

US3742395

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

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

Collection date (dd MMM yyyy)	20 JAN 2021
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Collection time (00:00-23:59)	08:49 (24 HR)
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Collection date and time (derived)	20 JAN 2021 08:49
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US3742395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00 - 23:59)	08:52
Collection Date and Time (derived)	20 JAN 2021 08:52

US3742395

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:14:51

Generated On: 12 Aug 2021 13:21:23

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

US3742395

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

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)	17 FEB 2021
Time of assessment (00:00-23:59)	08:57 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 08:57
Temperature (xxx.x)	098.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	062 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	069 mmHg
Diastolic Blood Pressure units	MMHG

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

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)	17 FEB 2021
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 09:37
Temperature (xxx.x)	097.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	066 mmHg
Diastolic Blood Pressure units	MMHG

US3742395

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 FEB 2021

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

US3742395

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

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) 17 FEB 2021

What was the treatment time? (00:00-23:59) 09:06 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 09:06

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

US3742395

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:48:15

Generated On: 12 Aug 2021 13:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:48:15

Generated On: 12 Aug 2021 13:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742395

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:48:14

Generated On: 12 Aug 2021 13:21:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:48:14

Generated On: 12 Aug 2021 13:21:23

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) _____

US3742395

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:48:14

Generated On: 12 Aug 2021 13:21:23

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.

US3742395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:48:14

Generated On: 12 Aug 2021 13:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

08:10 (24 HR)

Collection date and time (derived)

17 MAR 2021 08:10

US3742395

Folder: Unscheduled (1)

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:21:23

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3742395

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:57:29

Generated On: 12 Aug 2021 13:21:23

AEID	
Adverse event	DEEP VEIN THROMBOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:57:29

Generated On: 12 Aug 2021 13:21:23

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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	HAD FOLLOW-UP VISIT IN FEBRUARY, DR. TOLD HIM THIS IS A CHRONIC CONDITION AND HE WOULD BE TAKING ELIQUIS FOR LIFE.
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

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

Yes ☒

No ☐

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

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Name of Medication BIKTARVY- BICTEGRAVIR,
EMTRICITABINE, AND
TENOFIVIR

Prophylaxis Yes ☐
No ☒

Indication HUMAN IMMUNODEFICIENCY
VIRUS

Dose per administration 50/200/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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EAB) (1725)

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US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication DEEP VEIN THROMBOSIS

Dose per administration 100

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 (2)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		4 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

320 of 1591

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

	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)		06 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		06 OCT 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"/>

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication DEEP VEIN THROMBOSIS

Dose per administration 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 ☐

PRODUCTION RELEASE (v12.003

322 of 1591

EAB) (1725)

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

	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)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742395

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:48:14

Generated On: 12 Aug 2021 13:21:23

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3742395

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 07 Apr 2021 21:48:14

Generated On: 12 Aug 2021 13:21:23

Date of dosing discontinuation (dd MMM yyyy) 07 OCT 2020

Primary reason for dosing discontinuation

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

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

US3742395

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 23 Feb 2021 18:14:50

Generated On: 12 Aug 2021 13:21:23

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

US3742395 (Prod: University of Maryland School of Medicine)

US3742395

Form: Participant Creation

Generated On: 12 Aug 2021 13:21:23

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'US3742395'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:04:30

US3742395

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Sep 2020 14:31:26

US3742395

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:04:31

US3742395

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	17 Sep 2020 14:31:26

US3742395

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'SCRN'	System	17 Sep 2020 14:31:26

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:04:32

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '61'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User entered 'YEARS'	System	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User entered '61'	System	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Male (M)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User closed query 'Per CDM: Other has been selected for Race, however, please review the predefined options and update if appropriate' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:09:54
Query 'Per CDM: Other has been selected for Race, however, please review the predefined options and update if appropriate' answered with 'participant identifies as mulato' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 21:03:37
User opened query 'Per CDM: Other has been selected for Race, however, please review the predefined options and update if appropriate' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 01:28:38
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:52:13
User entered 'I'	Sherry McCammon (b) (4) (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 21:48:45
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	20 Apr 2021 21:03:17
	(b) (4)	
User entered 'Mulato' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	20 Apr 2021 21:03:17
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
	(b) (4)	
User entered 'NATIVE'	Sherry McCammon (b) (4)	17 Sep 2020 14:32:38
	(b) (4)	

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:21:23

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:59:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:32:38

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020'	Sherry McCammon (b) (4)	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'Sep 2020'	System	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '2020'	System	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Amendment 3 (3)'	Sherry McCammon (b) (4)	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:33:15

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:04:31

US3742395

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:21:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'I'	System	17 Sep 2020 14:33:22

US3742395

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:33:22

US3742395

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:21:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:29:47

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: Human immunodeficiency virus syndrome - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 19:52:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 19:52:42
Data point term sent to Coder	System	17 Sep 2020 17:32:43
User entered 'human immunodeficiency virus (HIV)'	Hassan Haji (b) (4)	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'UN UNK 1988'	Hassan Haji (b) (4)	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Hassan Haji (b) (4)	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Hassan Haji (b) (4)	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'Jan 1988'	System	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '1988'	System	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	17 Sep 2020 17:32:40

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:34:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:34:38
Data point term sent to Coder	System	17 Sep 2020 17:33:46
User entered 'allergy to penicillin'	Hassan Haji (b) (4)	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'UN UNK 1970'	Hassan Haji (b) (4)	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Hassan Haji (b) (4)	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Hassan Haji (b) (4)	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'Jan 1970'	System	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '1970'	System	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	17 Sep 2020 17:33:16

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Contrast media allergy, LLT: Contrast media allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 17:35:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:35:41
Data point term sent to Coder	System	17 Sep 2020 17:34:47
User entered 'allergy to contrast dye'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'UN UNK 1982'	Hassan Haji (b) (4)	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Hassan Haji (b) (4)	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Hassan Haji (b) (4)	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'Jan 1982'	System	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '1982'	System	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	17 Sep 2020 17:33:48

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User coded data point as SOC: Vascular disorders, HLGTT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:28:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 16:28:21
Data point term sent to Coder	System	06 Oct 2020 16:28:00
User entered 'DEEP VEIN THROMBOSIS' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Oct 2020 16:27:00
Data point term sent to Coder	System	06 Oct 2020 16:26:58
User entered 'DEEP'	Sherry McCammon (b) (4)	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'UN Feb 2019'	Sherry McCammon (b) (4)	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Sherry McCammon (b) (4)	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'UN Feb 2019'	Sherry McCammon (b) (4)	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Sherry McCammon (b) (4)	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'Feb 2019'	System	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '2019'	System	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'Feb 2019'	System	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '2019'	System	06 Oct 2020 16:26:44

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020'	Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '09:23'	Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '17 Sep 2020 09:23'	System	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '73.0' in	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:41:50
DataPoint set to visible.	(b) (4) System	17 Sep 2020 14:33:22

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '214.5' lb	Hassan Haji (b) (4)	17 Sep 2020 17:41:50
DataPoint set to visible.	System	17 Sep 2020 14:33:22

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '28.35904'	System	17 Sep 2020 17:41:50
DataPoint set to visible.	System	17 Sep 2020 14:33:22

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'kg/m2'	System	17 Sep 2020 17:41:50
DataPoint set to visible.	System	17 Sep 2020 14:33:22

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'bpm'	System	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'breaths/min'	System	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	17 Sep 2020 17:41:50

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57

US3742395

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57

US3742395

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:44

US3742395

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:44

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '0'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'I'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:21:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'ZIP CODE (b) (6)'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:35:10

US3742395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	(b) (4)	
	System	17 Sep 2020 14:36:44
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	17 Sep 2020 14:35:59
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	17 Sep 2020 14:36:44
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	17 Sep 2020 14:35:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:59

US3742395

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'VISIT1'	System	17 Sep 2020 14:35:59

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:19:43

US3742395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '114499'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:19:43

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:19:43

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Hassan Haji (b) (4)	17 Sep 2020 17:42:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Hassan Haji (b) (4)	17 Sep 2020 17:42:46

US3742395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Hassan Haji (b) (4)	17 Sep 2020 17:42:46

US3742395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Hassan Haji (b) (4)	17 Sep 2020 17:42:46

US3742395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:42:46

US3742395

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:21:23

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 18:50:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 18:50:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	22 Oct 2020 18:50:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Oct 2020 18:49:42
User entered empty.	System	22 Oct 2020 18:49:42
Amendment Manager: DataPoint set to visible.	Sherry McCammon (b) (4)	19 Sep 2020 09:24:05
Amendment Manager inserted this DataPoint.	(b) (4)	19 Sep 2020 09:24:04
	System	
	System	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '09:23'	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '17 Sep 2020 09:23'	System	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '097.3' F	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Other (Other)'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'TEMPORAL'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '062'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'bpm'	System	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '14'	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'breaths/min'	System	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '121'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'mmHg'	System	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Sep 2020 17:50:23
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 17:50:23
User entered '072' reason for change: Data Entry Error	Hassan Haji (b) (4)	17 Sep 2020 17:50:23
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	17 Sep 2020 17:49:57
User entered '112'	System	17 Sep 2020 17:49:57
	Hassan Haji (b) (4)	17 Sep 2020 17:49:57
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'mmHg'	System	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered missing code ND - Not Done.	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '11:01'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '17 Sep 2020 11:01'	System	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '98.4' F	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '060'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'bpm'	System	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '16'	(b) (4) Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'breaths/min'	System	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 17:50:49
User entered '112' reason for change: Data Entry Error	System	17 Sep 2020 17:50:49
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 17:49:57
User entered '072'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'mmHg'	System	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	(b) (4)	17 Sep 2020 17:50:49
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	17 Sep 2020 17:50:49
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	17 Sep 2020 17:49:57
User entered '079'	Hassan Haji (b) (4)	17 Sep 2020 17:49:57
	(b) (4)	

US3742395

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'mmHg'	System	17 Sep 2020 17:49:57

US3742395

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:35:48

US3742395

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	17 Sep 2020 14:35:48

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '10:30'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '17 Sep 2020 10:30'	System	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'ONCE'	System	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 14:40:17

US3742395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Sep 2020 14:33:44

US3742395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	17 Sep 2020 14:33:44

US3742395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '09:39'	Sherry McCammon (b) (4)	17 Sep 2020 14:33:44

US3742395

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '17 Sep 2020 09:39'	System	17 Sep 2020 14:33:44

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '17 Sep 2020'	Sherry McCammon (b) (4)	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '09:32'	Sherry McCammon (b) (4)	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '17 Sep 2020 09:32'	System	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	17 Sep 2020 14:34:05

US3742395

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 17:51:20

US3742395

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '1'	System	17 Sep 2020 17:51:20

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:01:25', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd3ee1e54-02ff-4e99-b553-98417757c3c5'	System	17 Sep 2020 15:01:49
User entered 'Yes (Y)'	System	17 Sep 2020 15:01:49

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:01:33', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd3ee1e54-02ff-4e99-b553-98417757c3c5'	System	17 Sep 2020 15:01:49
User entered '98.4'	System	17 Sep 2020 15:01:49

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:01:38', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd3ee1e54-02ff-4e99-b553-98417757c3c5'	System	17 Sep 2020 15:01:49
User entered 'No (N)'	System	17 Sep 2020 15:01:49

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:01:44', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd3ee1e54-02ff-4e99-b553-98417757c3c5'	System	17 Sep 2020 15:01:49
User entered '17 Sep 2020 11:01'	System	17 Sep 2020 15:01:49

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 10:50'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 13:20'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:00', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8ffadd46-d09b-4bd9-9ae9-b7bd2d18fefa'	System	17 Sep 2020 19:13:22
User entered 'Yes (Y)'	System	17 Sep 2020 19:13:22

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:09', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8ffadd46-d09b-4bd9-9ae9-b7bd2d18fefa'	System	17 Sep 2020 19:13:22
User entered '98.4'	System	17 Sep 2020 19:13:22

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:14', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8ffadd46-d09b-4bd9-9ae9-b7bd2d18fefa'	System	17 Sep 2020 19:13:22
User entered 'No (N)'	System	17 Sep 2020 19:13:22

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:18', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8ffadd46-d09b-4bd9-9ae9-b7bd2d18fefa'	System	17 Sep 2020 19:13:22
User entered '17 Sep 2020 15:13'	System	17 Sep 2020 19:13:22

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 14:15'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 2'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:05:30', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b474af23-b0a5-41d5-b0a1-d948c74bc53d'	System	19 Sep 2020 01:05:49
User entered 'Yes (Y)'	System	19 Sep 2020 01:05:49

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:05:36', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b474af23-b0a5-41d5-b0a1-d948c74bc53d'	System	19 Sep 2020 01:05:49
User entered '96.6'	System	19 Sep 2020 01:05:49

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:05:40', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b474af23-b0a5-41d5-b0a1-d948c74bc53d'	System	19 Sep 2020 01:05:49
User entered 'No (N)'	System	19 Sep 2020 01:05:49

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:05:44', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b474af23-b0a5-41d5-b0a1-d948c74bc53d'	System	19 Sep 2020 01:05:49
User entered '18 Sep 2020 21:05'	System	19 Sep 2020 01:05:49

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 3'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:05', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '93dc2b01-eb29-4b83-8ef8-a27fb07f4c49'	System	19 Sep 2020 23:13:28
User entered 'Yes (Y)'	System	19 Sep 2020 23:13:28

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:13', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '93dc2b01-eb29-4b83-8ef8-a27fb07f4c49'	System	19 Sep 2020 23:13:28
User entered '97.8'	System	19 Sep 2020 23:13:28

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:17', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '93dc2b01-eb29-4b83-8ef8-a27fb07f4c49'	System	19 Sep 2020 23:13:28
User entered 'No (N)'	System	19 Sep 2020 23:13:28

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:24', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '93dc2b01-eb29-4b83-8ef8-a27fb07f4c49'	System	19 Sep 2020 23:13:28
User entered '19 Sep 2020 19:13'	System	19 Sep 2020 23:13:28

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 4'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:17', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '40504e84-cd77-4f3e-bd32-2175922bddae'	System	21 Sep 2020 01:59:40
User entered 'Yes (Y)'	System	21 Sep 2020 01:59:40

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:31', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '40504e84-cd77-4f3e-bd32-2175922bddae'	System	21 Sep 2020 01:59:40
User entered '97.5'	System	21 Sep 2020 01:59:40

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:34', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '40504e84-cd77-4f3e-bd32-2175922bddae'	System	21 Sep 2020 01:59:40
User entered 'No (N)'	System	21 Sep 2020 01:59:40

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:37', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '40504e84-cd77-4f3e-bd32-2175922bddae'	System	21 Sep 2020 01:59:40
User entered '20 Sep 2020 21:59'	System	21 Sep 2020 01:59:40

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 5'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:10:52', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '15d9d32a-3f1f-4923-936e-143519d5911b'	System	22 Sep 2020 00:11:05
User entered 'Yes (Y)'	System	22 Sep 2020 00:11:05

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:10:56', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '15d9d32a-3f1f-4923-936e-143519d5911b'	System	22 Sep 2020 00:11:05
User entered '97.2'	System	22 Sep 2020 00:11:05

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:10:59', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '15d9d32a-3f1f-4923-936e-143519d5911b'	System	22 Sep 2020 00:11:05
User entered 'No (N)'	System	22 Sep 2020 00:11:05

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:02', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '15d9d32a-3f1f-4923-936e-143519d5911b'	System	22 Sep 2020 00:11:05
User entered '21 Sep 2020 20:11'	System	22 Sep 2020 00:11:05

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 6'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:10:39', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'cb5ef096-957b-46bf-ab43-0f62ab592f68'	System	23 Sep 2020 01:10:51
User entered 'Yes (Y)'	System	23 Sep 2020 01:10:51

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:10:42', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'cb5ef096-957b-46bf-ab43-0f62ab592f68'	System	23 Sep 2020 01:10:51
User entered '97.6'	System	23 Sep 2020 01:10:51

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:10:46', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'cb5ef096-957b-46bf-ab43-0f62ab592f68'	System	23 Sep 2020 01:10:51
User entered 'No (N)'	System	23 Sep 2020 01:10:51

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:10:50', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'cb5ef096-957b-46bf-ab43-0f62ab592f68'	System	23 Sep 2020 01:10:51
User entered '22 Sep 2020 21:10'	System	23 Sep 2020 01:10:51

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 7'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:15', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '471c3e3a-1a71-4021-9e4c-7e60c4b917de'	System	24 Sep 2020 00:15:31
User entered 'Yes (Y)'	System	24 Sep 2020 00:15:31

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:20', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '471c3e3a-1a71-4021-9e4c-7e60c4b917de' User entered '98.3'	System	24 Sep 2020 00:15:31
	System	24 Sep 2020 00:15:31

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:23', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '471c3e3a-1a71-4021-9e4c-7e60c4b917de'	System	24 Sep 2020 00:15:31
User entered 'No (N)'	System	24 Sep 2020 00:15:31

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:26', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '471c3e3a-1a71-4021-9e4c-7e60c4b917de'	System	24 Sep 2020 00:15:31
User entered '23 Sep 2020 20:15'	System	24 Sep 2020 00:15:31

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:01:56', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '3b77389b-e05d-4d6b-b905-6163bea3e53e'	System	17 Sep 2020 15:02:21
User entered 'None (1)'	System	17 Sep 2020 15:02:21

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:01:59', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '3b77389b-e05d-4d6b-b905-6163bea3e53e'	System	17 Sep 2020 15:02:21
User entered 'No (N)'	System	17 Sep 2020 15:02:21

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:02', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '3b77389b-e05d-4d6b-b905-6163bea3e53e'	System	17 Sep 2020 15:02:21
User entered 'No (N)'	System	17 Sep 2020 15:02:21

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:11', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '3b77389b-e05d-4d6b-b905-6163bea3e53e'	System	17 Sep 2020 15:02:21
User entered 'None (1)'	System	17 Sep 2020 15:02:21

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:16', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '3b77389b-e05d-4d6b-b905-6163bea3e53e'	System	17 Sep 2020 15:02:21
User entered '17 Sep 2020 11:02'	System	17 Sep 2020 15:02:21

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 10:50'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 13:20'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:24', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'c7c5e3b8-f081-4b93-81f0-c1d439e84000'	System	17 Sep 2020 19:13:44
User entered 'None (1)'	System	17 Sep 2020 19:13:44

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:28', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'c7c5e3b8-f081-4b93-81f0-c1d439e84000'	System	17 Sep 2020 19:13:44
User entered 'No (N)'	System	17 Sep 2020 19:13:44

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:31', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'c7c5e3b8-f081-4b93-81f0-c1d439e84000'	System	17 Sep 2020 19:13:44
User entered 'No (N)'	System	17 Sep 2020 19:13:44

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:35', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'c7c5e3b8-f081-4b93-81f0-c1d439e84000'	System	17 Sep 2020 19:13:44
User entered 'None (1)'	System	17 Sep 2020 19:13:44

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:39', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'c7c5e3b8-f081-4b93-81f0-c1d439e84000'	System	17 Sep 2020 19:13:44
User entered '17 Sep 2020 15:13'	System	17 Sep 2020 19:13:44

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 14:15'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 2'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:05:56', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1e1ca486-6b6a-49c2-860d-aa7182179c06'	System	19 Sep 2020 01:06:23
User entered 'None (1)'	System	19 Sep 2020 01:06:23

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:05:59', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1e1ca486-6b6a-49c2-860d-aa7182179c06'	System	19 Sep 2020 01:06:23
User entered 'No (N)'	System	19 Sep 2020 01:06:23

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:03', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1e1ca486-6b6a-49c2-860d-aa7182179c06'	System	19 Sep 2020 01:06:23
User entered 'No (N)'	System	19 Sep 2020 01:06:23

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:17', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1e1ca486-6b6a-49c2-860d-aa7182179c06'	System	19 Sep 2020 01:06:23
User entered 'None (1)'	System	19 Sep 2020 01:06:23

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:21', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1e1ca486-6b6a-49c2-860d-aa7182179c06'	System	19 Sep 2020 01:06:23
User entered '18 Sep 2020 21:06'	System	19 Sep 2020 01:06:23

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 3'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:30', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '13858ee6-db29-44b8-b8bb-e4080b637bf7'	System	19 Sep 2020 23:13:47
User entered 'None (1)'	System	19 Sep 2020 23:13:47

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:33', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '13858ee6-db29-44b8-b8bb-e4080b637bf7'	System	19 Sep 2020 23:13:47
User entered 'No (N)'	System	19 Sep 2020 23:13:47

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:36', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '13858ee6-db29-44b8-b8bb-e4080b637bf7'	System	19 Sep 2020 23:13:47
User entered 'No (N)'	System	19 Sep 2020 23:13:47

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:39', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '13858ee6-db29-44b8-b8bb-e4080b637bf7'	System	19 Sep 2020 23:13:47
User entered 'None (1)'	System	19 Sep 2020 23:13:47

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:43', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '13858ee6-db29-44b8-b8bb-e4080b637bf7'	System	19 Sep 2020 23:13:47
User entered '19 Sep 2020 19:13'	System	19 Sep 2020 23:13:47

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 4'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:42', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'edcb4f1a-15f4-4035-b800-ef96fdfef6bd'	System	21 Sep 2020 01:59:56
User entered 'None (1)'	System	21 Sep 2020 01:59:56

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:45', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'edcb4f1a-15f4-4035-b800-ef96fdfef6bd'	System	21 Sep 2020 01:59:56
User entered 'No (N)'	System	21 Sep 2020 01:59:56

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:48', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'edcb4f1a-15f4-4035-b800-ef96fdfe6bd'	System	21 Sep 2020 01:59:56
User entered 'No (N)'	System	21 Sep 2020 01:59:56

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:50', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'edcb4f1a-15f4-4035-b800-ef96fdfef6bd'	System	21 Sep 2020 01:59:56
User entered 'None (1)'	System	21 Sep 2020 01:59:56

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:53', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'edcb4f1a-15f4-4035-b800-ef96fdfef6bd'	System	21 Sep 2020 01:59:56
User entered '20 Sep 2020 21:59'	System	21 Sep 2020 01:59:56

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 5'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:06', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '7eb64083-87d2-4626-8f9e-7a090fd8e54c'	System	22 Sep 2020 00:11:19
User entered 'None (1)'	System	22 Sep 2020 00:11:19

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:09', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '7eb64083-87d2-4626-8f9e-7a090fd8e54c'	System	22 Sep 2020 00:11:19
User entered 'No (N)'	System	22 Sep 2020 00:11:19

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:12', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '7eb64083-87d2-4626-8f9e-7a090fd8e54c'	System	22 Sep 2020 00:11:19
User entered 'No (N)'	System	22 Sep 2020 00:11:19

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:15', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '7eb64083-87d2-4626-8f9e-7a090fd8e54c'	System	22 Sep 2020 00:11:19
User entered 'None (1)'	System	22 Sep 2020 00:11:19

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:18', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '7eb64083-87d2-4626-8f9e-7a090fd8e54c'	System	22 Sep 2020 00:11:19
User entered '21 Sep 2020 20:11'	System	22 Sep 2020 00:11:19

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 6'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:10:54', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '88252f89-d269-4189-bd3d-0448e6a83ebd'	System	23 Sep 2020 01:11:08
User entered 'None (1)'	System	23 Sep 2020 01:11:08

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:10:56', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '88252f89-d269-4189-bd3d-0448e6a83ebd'	System	23 Sep 2020 01:11:08
User entered 'No (N)'	System	23 Sep 2020 01:11:08

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:10:59', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '88252f89-d269-4189-bd3d-0448e6a83ebd'	System	23 Sep 2020 01:11:08
User entered 'No (N)'	System	23 Sep 2020 01:11:08

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:01', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '88252f89-d269-4189-bd3d-0448e6a83ebd'	System	23 Sep 2020 01:11:08
User entered 'None (1)'	System	23 Sep 2020 01:11:08

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:04', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '88252f89-d269-4189-bd3d-0448e6a83ebd'	System	23 Sep 2020 01:11:08
User entered '22 Sep 2020 21:11'	System	23 Sep 2020 01:11:08

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 7'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:30', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'a4bc9274-5892-4038-8c1e-519d3220e7d1'	System	24 Sep 2020 00:15:41
User entered 'None (1)'	System	24 Sep 2020 00:15:41

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:33', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'a4bc9274-5892-4038-8c1e-519d3220e7d1'	System	24 Sep 2020 00:15:41
User entered 'No (N)'	System	24 Sep 2020 00:15:41

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:35', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'a4bc9274-5892-4038-8c1e-519d3220e7d1'	System	24 Sep 2020 00:15:41
User entered 'No (N)'	System	24 Sep 2020 00:15:41

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:37', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'a4bc9274-5892-4038-8c1e-519d3220e7d1'	System	24 Sep 2020 00:15:41
User entered 'None (1)'	System	24 Sep 2020 00:15:41

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:40', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'a4bc9274-5892-4038-8c1e-519d3220e7d1'	System	24 Sep 2020 00:15:41
User entered '23 Sep 2020 20:15'	System	24 Sep 2020 00:15:41

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:25', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b8959e34-18ed-49cf-a0b6-e9328c777341'	System	17 Sep 2020 15:03:08
User entered 'None (0)'	System	17 Sep 2020 15:03:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:30', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b8959e34-18ed-49cf-a0b6-e9328c777341'	System	17 Sep 2020 15:03:08
User entered 'None (0)'	System	17 Sep 2020 15:03:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:33', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b8959e34-18ed-49cf-a0b6-e9328c777341'	System	17 Sep 2020 15:03:08
User entered 'None (0)'	System	17 Sep 2020 15:03:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:35', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b8959e34-18ed-49cf-a0b6-e9328c777341'	System	17 Sep 2020 15:03:08
User entered 'None (0)'	System	17 Sep 2020 15:03:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:37', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b8959e34-18ed-49cf-a0b6-e9328c777341'	System	17 Sep 2020 15:03:08
User entered 'None (0)'	System	17 Sep 2020 15:03:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:40', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b8959e34-18ed-49cf-a0b6-e9328c777341'	System	17 Sep 2020 15:03:08
User entered 'None (0)'	System	17 Sep 2020 15:03:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

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)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:02:58', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b8959e34-18ed-49cf-a0b6-e9328c777341'	System	17 Sep 2020 15:03:08
User entered 'No (N)'	System	17 Sep 2020 15:03:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T11:03:03', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'b8959e34-18ed-49cf-a0b6-e9328c777341'	System	17 Sep 2020 15:03:08
User entered '17 Sep 2020 11:03'	System	17 Sep 2020 15:03:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 10:50'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 13:20'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:45', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '65d507ba-6835-4e32-8013-2e64444bb972'	System	17 Sep 2020 19:14:20
User entered 'None (0)'	System	17 Sep 2020 19:14:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:49', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '65d507ba-6835-4e32-8013-2e64444bb972'	System	17 Sep 2020 19:14:20
User entered 'None (0)'	System	17 Sep 2020 19:14:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:51', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '65d507ba-6835-4e32-8013-2e64444bb972'	System	17 Sep 2020 19:14:20
User entered 'None (0)'	System	17 Sep 2020 19:14:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:54', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '65d507ba-6835-4e32-8013-2e64444bb972'	System	17 Sep 2020 19:14:20
User entered 'None (0)'	System	17 Sep 2020 19:14:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:13:57', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '65d507ba-6835-4e32-8013-2e64444bb972'	System	17 Sep 2020 19:14:20
User entered 'None (0)'	System	17 Sep 2020 19:14:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:14:00', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '65d507ba-6835-4e32-8013-2e64444bb972'	System	17 Sep 2020 19:14:20
User entered 'None (0)'	System	17 Sep 2020 19:14:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

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)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:14:11', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '65d507ba-6835-4e32-8013-2e64444bb972'	System	17 Sep 2020 19:14:20
User entered 'Yes (Y)'	System	17 Sep 2020 19:14:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-17T15:14:15', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '65d507ba-6835-4e32-8013-2e64444bb972'	System	17 Sep 2020 19:14:20
User entered '17 Sep 2020 15:14'	System	17 Sep 2020 19:14:20

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '17 Sep 2020 14:15'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 2'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:27', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '100f95fb-94ed-4445-861b-19e1ecb553da'	System	19 Sep 2020 01:06:57
User entered 'None (0)'	System	19 Sep 2020 01:06:57

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:31', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '100f95fb-94ed-4445-861b-19e1ecb553da'	System	19 Sep 2020 01:06:57
User entered 'None (0)'	System	19 Sep 2020 01:06:57

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:33', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '100f95fb-94ed-4445-861b-19e1ecb553da'	System	19 Sep 2020 01:06:57
User entered 'None (0)'	System	19 Sep 2020 01:06:57

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:36', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '100f95fb-94ed-4445-861b-19e1ecb553da'	System	19 Sep 2020 01:06:57
User entered 'None (0)'	System	19 Sep 2020 01:06:57

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:38', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '100f95fb-94ed-4445-861b-19e1ecb553da'	System	19 Sep 2020 01:06:57
User entered 'None (0)'	System	19 Sep 2020 01:06:57

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:40', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '100f95fb-94ed-4445-861b-19e1ecb553da'	System	19 Sep 2020 01:06:57
User entered 'None (0)'	System	19 Sep 2020 01:06:57

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

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)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:52', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '100f95fb-94ed-4445-861b-19e1ecb553da'	System	19 Sep 2020 01:06:57
User entered 'No (N)'	System	19 Sep 2020 01:06:57

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-18T21:06:55', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '100f95fb-94ed-4445-861b-19e1ecb553da'	System	19 Sep 2020 01:06:57
User entered '18 Sep 2020 21:06'	System	19 Sep 2020 01:06:57

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 3'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:48', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'e8ec636e-265c-4882-a93d-8545ce231872'	System	19 Sep 2020 23:14:08
User entered 'None (0)'	System	19 Sep 2020 23:14:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:50', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'e8ec636e-265c-4882-a93d-8545ce231872'	System	19 Sep 2020 23:14:08
User entered 'None (0)'	System	19 Sep 2020 23:14:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:52', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'e8ec636e-265c-4882-a93d-8545ce231872'	System	19 Sep 2020 23:14:08
User entered 'None (0)'	System	19 Sep 2020 23:14:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:54', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'e8ec636e-265c-4882-a93d-8545ce231872'	System	19 Sep 2020 23:14:08
User entered 'None (0)'	System	19 Sep 2020 23:14:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:56', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'e8ec636e-265c-4882-a93d-8545ce231872'	System	19 Sep 2020 23:14:08
User entered 'None (0)'	System	19 Sep 2020 23:14:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:13:58', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'e8ec636e-265c-4882-a93d-8545ce231872'	System	19 Sep 2020 23:14:08
User entered 'None (0)'	System	19 Sep 2020 23:14:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

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)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:14:04', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'e8ec636e-265c-4882-a93d-8545ce231872'	System	19 Sep 2020 23:14:08
User entered 'No (N)'	System	19 Sep 2020 23:14:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-19T19:14:07', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'e8ec636e-265c-4882-a93d-8545ce231872'	System	19 Sep 2020 23:14:08
User entered '19 Sep 2020 19:14'	System	19 Sep 2020 23:14:08

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 4'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T21:59:58', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8e1c45b8-0412-4cc5-9f3d-c618d3f493c7'	System	21 Sep 2020 02:00:21
User entered 'None (0)'	System	21 Sep 2020 02:00:21

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T22:00:00', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8e1c45b8-0412-4cc5-9f3d-c618d3f493c7'	System	21 Sep 2020 02:00:21
User entered 'None (0)'	System	21 Sep 2020 02:00:21

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T22:00:02', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8e1c45b8-0412-4cc5-9f3d-c618d3f493c7'	System	21 Sep 2020 02:00:21
User entered 'None (0)'	System	21 Sep 2020 02:00:21

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T22:00:04', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8e1c45b8-0412-4cc5-9f3d-c618d3f493c7'	System	21 Sep 2020 02:00:21
User entered 'None (0)'	System	21 Sep 2020 02:00:21

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T22:00:06', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8e1c45b8-0412-4cc5-9f3d-c618d3f493c7'	System	21 Sep 2020 02:00:21
User entered 'None (0)'	System	21 Sep 2020 02:00:21

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T22:00:08', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8e1c45b8-0412-4cc5-9f3d-c618d3f493c7'	System	21 Sep 2020 02:00:21
User entered 'None (0)'	System	21 Sep 2020 02:00:21

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

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)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T22:00:11', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8e1c45b8-0412-4cc5-9f3d-c618d3f493c7'	System	21 Sep 2020 02:00:21
User entered 'No (N)'	System	21 Sep 2020 02:00:21

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-20T22:00:14', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8e1c45b8-0412-4cc5-9f3d-c618d3f493c7'	System	21 Sep 2020 02:00:21
User entered '20 Sep 2020 22:00'	System	21 Sep 2020 02:00:21

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 5'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:22', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '5031ca03-b7e1-4548-bac4-fdfe10ce1c16'	System	22 Sep 2020 00:11:40
User entered 'None (0)'	System	22 Sep 2020 00:11:40

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:24', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '5031ca03-b7e1-4548-bac4-fdfe10ce1c16'	System	22 Sep 2020 00:11:40
User entered 'None (0)'	System	22 Sep 2020 00:11:40

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:27', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '5031ca03-b7e1-4548-bac4-fdfe10ce1c16'	System	22 Sep 2020 00:11:40
User entered 'None (0)'	System	22 Sep 2020 00:11:40

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:28', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '5031ca03-b7e1-4548-bac4-fdfe10ce1c16'	System	22 Sep 2020 00:11:40
User entered 'None (0)'	System	22 Sep 2020 00:11:40

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:30', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '5031ca03-b7e1-4548-bac4-fdfe10ce1c16'	System	22 Sep 2020 00:11:40
User entered 'None (0)'	System	22 Sep 2020 00:11:40

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:32', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '5031ca03-b7e1-4548-bac4-fdfe10ce1c16'	System	22 Sep 2020 00:11:40
User entered 'None (0)'	System	22 Sep 2020 00:11:40

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

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)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:36', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '5031ca03-b7e1-4548-bac4-fdfe10ce1c16'	System	22 Sep 2020 00:11:40
User entered 'No (N)'	System	22 Sep 2020 00:11:40

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-21T20:11:38', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '5031ca03-b7e1-4548-bac4-fdfe10ce1c16'	System	22 Sep 2020 00:11:40
User entered '21 Sep 2020 20:11'	System	22 Sep 2020 00:11:40

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 6'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:08', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd770c3ac-c594-4891-ac40-76a75928f7d1'	System	23 Sep 2020 01:11:23
User entered 'None (0)'	System	23 Sep 2020 01:11:23

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:09', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd770c3ac-c594-4891-ac40-76a75928f7d1'	System	23 Sep 2020 01:11:23
User entered 'None (0)'	System	23 Sep 2020 01:11:23

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:11', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd770c3ac-c594-4891-ac40-76a75928f7d1'	System	23 Sep 2020 01:11:23
User entered 'None (0)'	System	23 Sep 2020 01:11:23

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:13', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd770c3ac-c594-4891-ac40-76a75928f7d1'	System	23 Sep 2020 01:11:23
User entered 'None (0)'	System	23 Sep 2020 01:11:23

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:15', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd770c3ac-c594-4891-ac40-76a75928f7d1'	System	23 Sep 2020 01:11:23
User entered 'None (0)'	System	23 Sep 2020 01:11:23

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:17', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd770c3ac-c594-4891-ac40-76a75928f7d1'	System	23 Sep 2020 01:11:23
User entered 'None (0)'	System	23 Sep 2020 01:11:23

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

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)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:19', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd770c3ac-c594-4891-ac40-76a75928f7d1'	System	23 Sep 2020 01:11:23
User entered 'No (N)'	System	23 Sep 2020 01:11:23

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-22T21:11:22', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'd770c3ac-c594-4891-ac40-76a75928f7d1'	System	23 Sep 2020 01:11:23
User entered '22 Sep 2020 21:11'	System	23 Sep 2020 01:11:23

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 7'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:44', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8be418d1-0c4b-4536-a427-65a8342626bd' User entered 'None (0)'	System	24 Sep 2020 00:15:59
	System	24 Sep 2020 00:15:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:46', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8be418d1-0c4b-4536-a427-65a8342626bd'	System	24 Sep 2020 00:15:59
User entered 'None (0)'	System	24 Sep 2020 00:15:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:48', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8be418d1-0c4b-4536-a427-65a8342626bd'	System	24 Sep 2020 00:15:59
User entered 'None (0)'	System	24 Sep 2020 00:15:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:50', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8be418d1-0c4b-4536-a427-65a8342626bd' User entered 'None (0)'	System	24 Sep 2020 00:15:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:52', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8be418d1-0c4b-4536-a427-65a8342626bd'	System	24 Sep 2020 00:15:59
User entered 'None (0)'	System	24 Sep 2020 00:15:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:54', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8be418d1-0c4b-4536-a427-65a8342626bd'	System	24 Sep 2020 00:15:59
User entered 'None (0)'	System	24 Sep 2020 00:15:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

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)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:56', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8be418d1-0c4b-4536-a427-65a8342626bd'	System	24 Sep 2020 00:15:59
User entered 'No (N)'	System	24 Sep 2020 00:15:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-09-23T20:15:59', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8be418d1-0c4b-4536-a427-65a8342626bd'	System	24 Sep 2020 00:15:59
User entered '23 Sep 2020 20:15'	System	24 Sep 2020 00:15:59

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 14:40:17

US3742395

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:21:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Sep 2020 15:17:46

US3742395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '24 Sep 2020'	Sherry McCammon (b) (4)	24 Sep 2020 15:17:46

US3742395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	24 Sep 2020 15:17:46

US3742395

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	24 Sep 2020 15:17:46

US3742395

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Sep 2020 15:17:57

US3742395

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'I'	System	24 Sep 2020 15:17:57

US3742395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	06 Oct 2020 16:17:20

US3742395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '1 Oct 2020'	Sherry McCammon (b) (4)	06 Oct 2020 16:17:20

US3742395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:17:20

US3742395

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:17:20

US3742395

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	06 Oct 2020 16:17:25

US3742395

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'I'	System	06 Oct 2020 16:17:25

US3742395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:42:23

US3742395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:42:23

US3742395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:42:23

US3742395

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:42:23

US3742395

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:42:32

US3742395

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'I'	System	08 Oct 2020 18:42:32

US3742395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Oct 2020 18:51:35

US3742395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	22 Oct 2020 18:52:05
User entered '15 Oct 2020' reason for change: Data Entry Error	System	22 Oct 2020 18:52:05
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	Sherry McCammon (b) (4)	22 Oct 2020 18:52:05
User entered '17 Sep 2020'	(b) (4)	
	System	22 Oct 2020 18:51:35
	Sherry McCammon (b) (4)	22 Oct 2020 18:51:35
	(b) (4)	

US3742395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	22 Oct 2020 18:51:35

US3742395

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'VISIT2'	System	22 Oct 2020 18:51:35

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05
	(b) (4)	

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '15 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '09:14'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '15 Oct 2020 09:14'	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '097.3' F	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Other (Other)'	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'temporal'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '080'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'bpm'	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '14'	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'breaths/min'	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '111'	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'mmHg'	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '073'	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'mmHg'	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4) (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 18:59:05

US3742395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:53:41

US3742395

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '15 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:53:41

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 19:12:34

US3742395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 15 OCT 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 12:40:49
Query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 15 OCT 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC. Thank you.' answered with 'UNSCHEDULED VISIT KIT USED FOR D29 DUE TO SHORTAGE OF KIT A. CONFIRM THAT DAY 29 IS CORRECT' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Nov 2020 15:11:53
User opened query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 15 OCT 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 11:51:16
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	22 Oct 2020 18:53:28

US3742395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '15 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	22 Oct 2020 18:53:28

US3742395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '09:08'	Sherry McCammon (b) (4)	22 Oct 2020 18:53:28

US3742395

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '15 Oct 2020 09:08'	System	22 Oct 2020 18:53:28

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 15OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 02:03:10
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 15OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' answered with 'Unscheduled Visit kit used for Day 29 visit due to shortage of Kit A at site. Confirmed that sample is for D29, NOT unscheduled visit. ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	30 Oct 2020 15:00:38
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 15OCT2020is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:18:57
User entered '15 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '09:17'	Sherry McCammon (b) (4)	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '15 Oct 2020 09:17'	System	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	Sherry McCammon (b) (4)	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	22 Oct 2020 18:53:00

US3742395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	22 Oct 2020 19:10:04
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	22 Oct 2020 19:07:07
	(b) (4)	

US3742395

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '1'	System	22 Oct 2020 19:10:04
User entered empty.	System	22 Oct 2020 19:07:07

US3742395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:19:24

US3742395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:19:24

US3742395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:19:24

US3742395

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:19:24

US3742395

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:19:55

US3742395

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'I'	System	29 Oct 2020 16:19:55

US3742395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:20:07

US3742395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:20:07

US3742395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:20:07

US3742395

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:20:07

US3742395

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:20:11

US3742395

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '1'	System	29 Oct 2020 16:20:11

US3742395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 09:38:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 16:59:39
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:14:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 12NOV2020. Please clarify and update if appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:14:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 12NOV2020. Please clarify and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:13:42
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	05 Nov 2020 20:25:02

US3742395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '5 Nov 2020'	Hassan Haji (b) (4)	05 Nov 2020 20:25:02

US3742395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	05 Nov 2020 20:25:02

US3742395

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	05 Nov 2020 20:25:02

US3742395

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Hassan Haji (b) (4)	05 Nov 2020 20:25:07

US3742395

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '1'	System	05 Nov 2020 20:25:07

US3742395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 17:08:37

US3742395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered '12 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	04 Dec 2020 17:08:37

US3742395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	04 Dec 2020 17:08:37

US3742395

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'VISIT3'	System	04 Dec 2020 17:08:37

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered empty.	System	04 Dec 2020 17:09:22

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58

US3742395

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58

US3742395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered 'No (N)'	Sherry McCammon (b) (4)	04 Dec 2020 17:09:07

US3742395

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Sherry McCammon (b) (4)	04 Dec 2020 17:09:07

US3742395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 17:08:53

US3742395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '12 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	04 Dec 2020 17:08:53

US3742395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered '08:51'	Sherry McCammon (b) (4)	04 Dec 2020 17:08:53

US3742395

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '12 Nov 2020 08:51'	System	04 Dec 2020 17:08:53

US3742395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:52:13
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Dec 2020 17:09:29

US3742395

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered '1'	System	04 Dec 2020 17:09:29

US3742395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
DataPoint Activated.	System	08 Oct 2020 18:39:29
DataPoint Inactivated.	System	07 Oct 2020 12:58:47
Data entry locked.	System	17 Sep 2020 14:40:17
User entered 'Day 64'	System	17 Sep 2020 14:40:17

US3742395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-11-17T09:05:14', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '29373bbb-a4d0-4ac4-b7a5-2e2184857df4'	System	17 Nov 2020 14:05:37
User entered 'No (N)'	System	17 Nov 2020 14:05:37
DataPoint Activated.	System	08 Oct 2020 18:39:29
DataPoint Inactivated.	System	07 Oct 2020 12:58:47

US3742395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-11-17T09:05:23', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '29373bbb-a4d0-4ac4-b7a5-2e2184857df4'	System	17 Nov 2020 14:05:37
User entered 'No (N)'	System	17 Nov 2020 14:05:37
DataPoint Activated.	System	08 Oct 2020 18:39:29
DataPoint Inactivated.	System	07 Oct 2020 12:58:47

US3742395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-11-17T09:05:30', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '29373bbb-a4d0-4ac4-b7a5-2e2184857df4'	System	17 Nov 2020 14:05:37
User entered '17 Nov 2020 09:05:30'	System	17 Nov 2020 14:05:37
DataPoint Activated.	System	08 Oct 2020 18:39:29
DataPoint Inactivated.	System	07 Oct 2020 12:58:47

US3742395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
DataPoint Activated.	System	08 Oct 2020 18:39:29
DataPoint Inactivated.	System	07 Oct 2020 12:58:47
Data entry locked.	System	17 Sep 2020 14:40:17
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 14:40:17

US3742395

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:51:07
DataPoint Activated.	System	08 Oct 2020 18:39:29
DataPoint Inactivated.	System	07 Oct 2020 12:58:47
Data entry locked.	System	17 Sep 2020 14:40:17
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 14:40:17

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2020-11-21T10:50:57', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '27e85c5e-768c-4a44-b577-27a147133929'	System	21 Nov 2020 15:51:08
User entered 'No (N)'	System	21 Nov 2020 15:51:08

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2020-11-21T10:51:02', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '27e85c5e-768c-4a44-b577-27a147133929'	System	21 Nov 2020 15:51:08
User entered 'No (N)'	System	21 Nov 2020 15:51:08

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-11-21T10:51:06', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '27e85c5e-768c-4a44-b577-27a147133929'	System	21 Nov 2020 15:51:08
User entered '21 Nov 2020 10:51:06'	System	21 Nov 2020 15:51:08

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2020-11-28T10:01:29', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'bc417363-e777-4a44-9b90-e5038068137c'	System	28 Nov 2020 15:01:39
User entered 'No (N)'	System	28 Nov 2020 15:01:39

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2020-11-28T10:01:34', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'bc417363-e777-4a44-9b90-e5038068137c'	System	28 Nov 2020 15:01:39
User entered 'No (N)'	System	28 Nov 2020 15:01:39

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-11-28T10:01:38', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'bc417363-e777-4a44-9b90-e5038068137c'	System	28 Nov 2020 15:01:39
User entered '28 Nov 2020 10:01:38'	System	28 Nov 2020 15:01:39

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2020-12-05T11:24:17', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1c3b3a1b-df2f-4671-9297-72a8d8e47cf3'	System	05 Dec 2020 16:24:24
User entered 'No (N)'	System	05 Dec 2020 16:24:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2020-12-05T11:24:22', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1c3b3a1b-df2f-4671-9297-72a8d8e47cf3'	System	05 Dec 2020 16:24:24
User entered 'No (N)'	System	05 Dec 2020 16:24:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-12-05T11:24:24', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1c3b3a1b-df2f-4671-9297-72a8d8e47cf3'	System	05 Dec 2020 16:24:24
User entered '05 Dec 2020 11:24:24'	System	05 Dec 2020 16:24:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2020-12-12T07:27:29', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '483d4704-03af-4e53-9f4b-6c7bd9c8065e'	System	12 Dec 2020 12:27:40
User entered 'No (N)'	System	12 Dec 2020 12:27:40

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2020-12-12T07:27:33', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '483d4704-03af-4e53-9f4b-6c7bd9c8065e'	System	12 Dec 2020 12:27:40
User entered 'No (N)'	System	12 Dec 2020 12:27:40

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-12-12T07:27:35', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '483d4704-03af-4e53-9f4b-6c7bd9c8065e'	System	12 Dec 2020 12:27:40
User entered '12 Dec 2020 07:27:35'	System	12 Dec 2020 12:27:40

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2020-12-19T13:43:26', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0a2d81f5-d967-4f05-9d9d-222cc0a25d8c'	System	19 Dec 2020 18:43:36
User entered 'No (N)'	System	19 Dec 2020 18:43:36

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2020-12-19T13:43:29', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0a2d81f5-d967-4f05-9d9d-222cc0a25d8c'	System	19 Dec 2020 18:43:36
User entered 'No (N)'	System	19 Dec 2020 18:43:36

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-12-19T13:43:31', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0a2d81f5-d967-4f05-9d9d-222cc0a25d8c'	System	19 Dec 2020 18:43:36
User entered '19 Dec 2020 13:43:31'	System	19 Dec 2020 18:43:36

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2020-12-26T07:24:23', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0e23d9f4-18f4-48aa-9a8e-2ad114695d8d'	System	26 Dec 2020 12:24:27
User entered 'No (N)'	System	26 Dec 2020 12:24:27

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2020-12-26T07:24:25', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0e23d9f4-18f4-48aa-9a8e-2ad114695d8d'	System	26 Dec 2020 12:24:27
User entered 'No (N)'	System	26 Dec 2020 12:24:27

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2020-12-26T07:24:27', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0e23d9f4-18f4-48aa-9a8e-2ad114695d8d'	System	26 Dec 2020 12:24:27
User entered '26 Dec 2020 07:24:27'	System	26 Dec 2020 12:24:27

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-01-02T18:11:23', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '3036b131-f0db-4cf6-9531-1ef4f4973f77'	System	02 Jan 2021 23:11:34
User entered 'No (N)'	System	02 Jan 2021 23:11:34

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-01-02T18:11:25', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '3036b131-f0db-4cf6-9531-1ef4f4973f77'	System	02 Jan 2021 23:11:34
User entered 'No (N)'	System	02 Jan 2021 23:11:34

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-01-02T18:11:30', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '3036b131-f0db-4cf6-9531-1ef4f4973f77'	System	02 Jan 2021 23:11:34
User entered '02 Jan 2021 18:11:30'	System	02 Jan 2021 23:11:34

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-01-09T12:22:14', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0fdd5ab4-538f-464e-80b8-a064fa94f023'	System	09 Jan 2021 17:22:24
User entered 'No (N)'	System	09 Jan 2021 17:22:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-01-09T12:22:18', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0fdd5ab4-538f-464e-80b8-a064fa94f023'	System	09 Jan 2021 17:22:24
User entered 'No (N)'	System	09 Jan 2021 17:22:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-01-09T12:22:20', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '0fdd5ab4-538f-464e-80b8-a064fa94f023'	System	09 Jan 2021 17:22:24
User entered '09 Jan 2021 12:22:20'	System	09 Jan 2021 17:22:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-01-16T00:03:47', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '434863c4-3ce2-4748-84e5-c3a624584382'	System	16 Jan 2021 05:05:58
User entered 'No (N)'	System	16 Jan 2021 05:05:58

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-01-16T00:03:50', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '434863c4-3ce2-4748-84e5-c3a624584382'	System	16 Jan 2021 05:05:58
User entered 'No (N)'	System	16 Jan 2021 05:05:58

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-01-16T00:03:52', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '434863c4-3ce2-4748-84e5-c3a624584382'	System	16 Jan 2021 05:05:58
User entered '16 Jan 2021 00:03:52'	System	16 Jan 2021 05:05:58

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-01-23T11:40:16', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '2561ee69-0606-4630-9d61-55fe83d3fe62'	System	23 Jan 2021 16:40:24
User entered 'No (N)'	System	23 Jan 2021 16:40:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-01-23T11:40:20', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '2561ee69-0606-4630-9d61-55fe83d3fe62'	System	23 Jan 2021 16:40:24
User entered 'No (N)'	System	23 Jan 2021 16:40:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-01-23T11:40:23', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '2561ee69-0606-4630-9d61-55fe83d3fe62'	System	23 Jan 2021 16:40:24
User entered '23 Jan 2021 11:40:23'	System	23 Jan 2021 16:40:24

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-01-30T06:10:43', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'fb695e3d-f320-4930-b832-9b119a1f38ff'	System	30 Jan 2021 11:10:47
User entered 'No (N)'	System	30 Jan 2021 11:10:47

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-01-30T06:10:46', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'fb695e3d-f320-4930-b832-9b119a1f38ff'	System	30 Jan 2021 11:10:47
User entered 'No (N)'	System	30 Jan 2021 11:10:47

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-01-30T06:10:49', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'fb695e3d-f320-4930-b832-9b119a1f38ff' User entered '30 Jan 2021 06:10:49'	System	30 Jan 2021 11:10:47
	System	30 Jan 2021 11:10:47

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-02-06T11:43:45', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '262081dd-6e61-4a2a-b312-b748d643c184'	System	06 Feb 2021 16:43:55
User entered 'No (N)'	System	06 Feb 2021 16:43:55

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-02-06T11:43:48', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '262081dd-6e61-4a2a-b312-b748d643c184'	System	06 Feb 2021 16:43:55
User entered 'No (N)'	System	06 Feb 2021 16:43:55

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-02-06T11:43:51', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '262081dd-6e61-4a2a-b312-b748d643c184'	System	06 Feb 2021 16:43:55
User entered '06 Feb 2021 11:43:51'	System	06 Feb 2021 16:43:55

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-02-13T08:26:29', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '603aebb5-5662-4684-bbe9-fccc6344e8f2'	System	13 Feb 2021 13:26:37
User entered 'No (N)'	System	13 Feb 2021 13:26:37

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-02-13T08:26:32', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '603aebb5-5662-4684-bbe9-fccc6344e8f2'	System	13 Feb 2021 13:26:37
User entered 'No (N)'	System	13 Feb 2021 13:26:37

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-02-13T08:26:36', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '603aebb5-5662-4684-bbe9-fccc6344e8f2'	System	13 Feb 2021 13:26:37
User entered '13 Feb 2021 08:26:36'	System	13 Feb 2021 13:26:37

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-02-20T06:16:47', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '857699e5-c3c7-43db-bf3f-ac058d7dde86'	System	20 Feb 2021 11:16:56
User entered 'No (N)'	System	20 Feb 2021 11:16:56

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-02-20T06:16:50', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '857699e5-c3c7-43db-bf3f-ac058d7dde86'	System	20 Feb 2021 11:16:56
User entered 'No (N)'	System	20 Feb 2021 11:16:56

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-02-20T06:16:52', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '857699e5-c3c7-43db-bf3f-ac058d7dde86'	System	20 Feb 2021 11:16:56
User entered '20 Feb 2021 06:16:52'	System	20 Feb 2021 11:16:56

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-02-27T08:45:25', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '954fe441-e85e-47fa-ad0b-a50277da9b78'	System	27 Feb 2021 13:45:31
User entered 'No (N)'	System	27 Feb 2021 13:45:31

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-02-27T08:45:28', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '954fe441-e85e-47fa-ad0b-a50277da9b78'	System	27 Feb 2021 13:45:31
User entered 'No (N)'	System	27 Feb 2021 13:45:31

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-02-27T08:45:30', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '954fe441-e85e-47fa-ad0b-a50277da9b78'	System	27 Feb 2021 13:45:31
User entered '27 Feb 2021 08:45:30'	System	27 Feb 2021 13:45:31

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-03-06T09:31:44', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '29d24125-2c5c-400e-a057-95e47891ca1f'	System	06 Mar 2021 14:31:55
User entered 'No (N)'	System	06 Mar 2021 14:31:55

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-03-06T09:31:49', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '29d24125-2c5c-400e-a057-95e47891ca1f'	System	06 Mar 2021 14:31:55
User entered 'No (N)'	System	06 Mar 2021 14:31:55

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-03-06T09:31:52', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '29d24125-2c5c-400e-a057-95e47891ca1f'	System	06 Mar 2021 14:31:55
User entered '06 Mar 2021 09:31:52'	System	06 Mar 2021 14:31:55

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-03-13T08:18:22', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '14f3daa5-9f04-486f-8d49-a43c3d354b5d'	System	13 Mar 2021 13:18:31
User entered 'No (N)'	System	13 Mar 2021 13:18:31

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-03-13T08:18:27', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '14f3daa5-9f04-486f-8d49-a43c3d354b5d'	System	13 Mar 2021 13:18:31
User entered 'No (N)'	System	13 Mar 2021 13:18:31

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-03-13T08:18:29', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '14f3daa5-9f04-486f-8d49-a43c3d354b5d'	System	13 Mar 2021 13:18:31
User entered '13 Mar 2021 08:18:29'	System	13 Mar 2021 13:18:31

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-03-20T10:22:59', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8ad7bd90-0302-4935-b4ea-34e49a0f4b3d'	System	20 Mar 2021 14:23:08
User entered 'No (N)'	System	20 Mar 2021 14:23:08

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-03-20T10:23:02', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8ad7bd90-0302-4935-b4ea-34e49a0f4b3d'	System	20 Mar 2021 14:23:08
User entered 'No (N)'	System	20 Mar 2021 14:23:08

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-03-20T10:23:04', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '8ad7bd90-0302-4935-b4ea-34e49a0f4b3d' User entered '20 Mar 2021 10:23:04'	System	20 Mar 2021 14:23:08
	System	20 Mar 2021 14:23:08

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-03-27T00:23:16', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '765733e5-55f9-444f-ac8c-76ca487d67ba'	System	27 Mar 2021 04:24:48
User entered 'No (N)'	System	27 Mar 2021 04:24:48

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-03-27T00:23:19', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '765733e5-55f9-444f-ac8c-76ca487d67ba'	System	27 Mar 2021 04:24:48
User entered 'No (N)'	System	27 Mar 2021 04:24:48

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-03-27T00:23:22', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '765733e5-55f9-444f-ac8c-76ca487d67ba'	System	27 Mar 2021 04:24:48
User entered '27 Mar 2021 00:23:22'	System	27 Mar 2021 04:24:48

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-04-03T08:14:17', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '198ccdf2-2df4-4215-99fc-a442b24e87f2'	System	03 Apr 2021 12:14:20
User entered 'No (N)'	System	03 Apr 2021 12:14:20

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-04-03T08:14:19', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '198ccdf2-2df4-4215-99fc-a442b24e87f2'	System	03 Apr 2021 12:14:20
User entered 'No (N)'	System	03 Apr 2021 12:14:20

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-04-03T08:14:22', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '198ccdf2-2df4-4215-99fc-a442b24e87f2'	System	03 Apr 2021 12:14:20
User entered '03 Apr 2021 08:14:22'	System	03 Apr 2021 12:14:20

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-04-10T11:46:09', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '44996db5-734c-4e8d-9d31-68b762f17d07'	System	10 Apr 2021 15:46:18
User entered 'No (N)'	System	10 Apr 2021 15:46:18

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-04-10T11:46:12', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '44996db5-734c-4e8d-9d31-68b762f17d07'	System	10 Apr 2021 15:46:18
User entered 'No (N)'	System	10 Apr 2021 15:46:18

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-04-10T11:46:15', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '44996db5-734c-4e8d-9d31-68b762f17d07'	System	10 Apr 2021 15:46:18
User entered '10 Apr 2021 11:46:15'	System	10 Apr 2021 15:46:18

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-04-17T07:29:29', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '7ad05f8f-ebe1-4bee-8f13-c080aa2b5bf1'	System	17 Apr 2021 11:29:37
User entered 'No (N)'	System	17 Apr 2021 11:29:37

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-04-17T07:29:32', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '7ad05f8f-ebc1-4bee-8f13-c080aa2b5bf1'	System	17 Apr 2021 11:29:37
User entered 'No (N)'	System	17 Apr 2021 11:29:37

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-04-17T07:29:34', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '7ad05f8f-ebel-4bee-8f13-c080aa2b5bf1' User entered '17 Apr 2021 07:29:34'	System	17 Apr 2021 11:29:37
	System	17 Apr 2021 11:29:37

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-04-24T10:06:17', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1d79b50d-8ce8-4ae4-95f9-940bcd50eea0'	System	24 Apr 2021 14:06:33
User entered 'No (N)'	System	24 Apr 2021 14:06:33

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-04-24T10:06:20', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1d79b50d-8ce8-4ae4-95f9-940bcd50eea0'	System	24 Apr 2021 14:06:33
User entered 'No (N)'	System	24 Apr 2021 14:06:33

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-04-24T10:06:22', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '1d79b50d-8ce8-4ae4-95f9-940bcd50eea0'	System	24 Apr 2021 14:06:33
User entered '24 Apr 2021 10:06:22'	System	24 Apr 2021 14:06:33

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[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 (887b9c21e060cb62)', Time: '2021-05-01T09:37:19', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '4588f128-b2e1-47e4-84cc-df68474f3748'	System	01 May 2021 13:37:27
User entered 'No (N)'	System	01 May 2021 13:37:27

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

Have you been exposed to someone with 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 (887b9c21e060cb62)', Time: '2021-05-01T09:37:21', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '4588f128-b2e1-47e4-84cc-df68474f3748'	System	01 May 2021 13:37:27
User entered 'No (N)'	System	01 May 2021 13:37:27

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-05-01T09:37:24', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: '4588f128-b2e1-47e4-84cc-df68474f3748'	System	01 May 2021 13:37:27
User entered '01 May 2021 09:37:24'	System	01 May 2021 13:37:27

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:09:07

US3742395

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:21:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:09:07
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:09:07

US3742395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:21:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:15:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-03-06T09:32:02', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'dc7c5e23-7ee1-4a45-a043-5d36e17b6388'	System	06 Mar 2021 14:32:10
User entered 'No (N)'	System	06 Mar 2021 14:32:10

US3742395

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:21:23

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:15:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (887b9c21e060cb62)', Time: '2021-03-06T09:32:07', User OID: 'PatientReportedOutcome (US3742395)', ODM File OID: 'dc7c5e23-7ee1-4a45-a043-5d36e17b6388'	System	06 Mar 2021 14:32:10
User entered '06 Mar 2021 09:32:07'	System	06 Mar 2021 14:32:10

US3742395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Hassan Haji (b) (4)	09 Dec 2020 18:59:08

US3742395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '9 Dec 2020'	Hassan Haji (b) (4)	09 Dec 2020 18:59:08

US3742395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	09 Dec 2020 18:59:08

US3742395

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	Hassan Haji (b) (4)	09 Dec 2020 18:59:08

US3742395

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Hassan Haji (b) (4)	09 Dec 2020 18:59:12

US3742395

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 23:53:58
User entered 'I'	System	09 Dec 2020 18:59:12

US3742395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Hassan Haji (b) (4)	14 Jan 2021 18:36:28

US3742395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '13 Jan 2021'	Hassan Haji (b) (4)	14 Jan 2021 18:36:28

US3742395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	14 Jan 2021 18:36:28

US3742395

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	Hassan Haji (b) (4)	14 Jan 2021 18:36:28

US3742395

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Hassan Haji (b) (4)	14 Jan 2021 18:36:12

US3742395

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User entered '1'	System	14 Jan 2021 18:36:12

US3742395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 15:01:16

US3742395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '12 Feb 2021'	Sherry McCammon (b) (4)	15 Feb 2021 15:01:16

US3742395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 15:01:16

US3742395

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	Sherry McCammon (b) (4)	15 Feb 2021 15:01:16

US3742395

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	15 Feb 2021 15:01:21

US3742395

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:09:02
User entered '1'	System	15 Feb 2021 15:01:21

US3742395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 13:49:29

US3742395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
	(b) (4)	
User entered '15 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 13:49:29

US3742395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Mar 2021 13:49:29

US3742395

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 13:49:29

US3742395

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 13:49:34

US3742395

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:52
User entered 'I'	System	16 Mar 2021 13:49:34

US3742395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:19:22

US3742395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:19:22

US3742395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:19:22

US3742395

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	15 Apr 2021 14:19:22

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 14:20:59

US3742395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:34

US3742395

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:34

US3742395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:15

US3742395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:15

US3742395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered '08:40'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:20:15

US3742395

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
User entered '15 Apr 2021 08:40'	System	15 Apr 2021 14:20:15

US3742395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	15 Apr 2021 22:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:19:42

US3742395

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 14:19:42

US3742395

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

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:36:09
	(b) (4), (b) (6)	

US3742395

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

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '20 Jan 2021'	(b) (4)	20 Jan 2021 17:36:09
	(b) (4), (b) (6)	

US3742395

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

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Clinic (Clinic)'	(b) (4)	20 Jan 2021 17:36:09
	(b) (4), (b) (6)	

US3742395

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

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 17:36:09

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:54
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:35
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 17:03:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:37:19

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:54
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:35:19

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:37:19
	(b) (4), (b) (6)	

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:49:54
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:03:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:35:19

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '20 Jan 2021'	(b) (4)	20 Jan 2021 17:37:19
	(b) (4), (b) (6)	

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:37:19

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:37:19

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:37:19

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:37:19
	(b) (4), (b) (6)	

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '1'	System	20 Jan 2021 17:37:19

US3742395

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

Form: Unblinding

Generated On: 12 Aug 2021 13:21:23

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'I'	System	20 Jan 2021 17:37:19

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered missing code ND - Not Done.	(b) (4)	20 Jan 2021 17:40:19
	(b) (4), (b) (6)	

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	20 Jan 2021 17:40:19
DataPoint set to visible.	System	20 Jan 2021 17:37:19

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered missing code ND - Not Done.	(b) (4)	20 Jan 2021 17:40:19
	(b) (4), (b) (6)	

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	20 Jan 2021 17:40:19
DataPoint set to visible.	System	20 Jan 2021 17:37:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '09:07'	(b) (4)	20 Jan 2021 17:40:19
	(b) (4), (b) (6)	

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '20 Jan 2021 09:07'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Oral (Oral)'	(b) (4)	20 Jan 2021 17:40:19
	(b) (4), (b) (6)	

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4)	20 Jan 2021 17:40:19
	(b) (4), (b) (6)	

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '065'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'bpm'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '12'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'breaths/min'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '116'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '066'	(b) (4)	20 Jan 2021 17:40:19
	(b) (4), (b) (6)	

US3742395

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:21:23

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered empty.	System	20 Jan 2021 17:40:19
DataPoint set to visible.	System	20 Jan 2021 17:37:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '09:47'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '20 Jan 2021 09:47'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4)	20 Jan 2021 17:40:19
	(b) (4), (b) (6)	

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '061'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'bpm'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '14'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'breaths/min'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '125'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '079'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:40:19

US3742395

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	20 Jan 2021 17:40:19

US3742395

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:37:51

US3742395

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '20 Jan 2021'	(b) (4)	20 Jan 2021 17:37:51
	(b) (4), (b) (6)	

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:38:11
	(b) (4), (b) (6)	

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4)	20 Jan 2021 17:38:11
	(b) (4), (b) (6)	

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:38:11

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mRNA-1273'	System	20 Jan 2021 17:38:11
DataPoint set to visible.	System	20 Jan 2021 17:37:19

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:38:11

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '09:16'	(b) (4)	20 Jan 2021 17:38:11
	(b) (4), (b) (6)	

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '20 Jan 2021 09:16'	System	20 Jan 2021 17:38:11

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:38:11

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'ONCE'	System	20 Jan 2021 17:38:11

US3742395

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

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 17:38:11

US3742395

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:36:26
	(b) (4), (b) (6)	

US3742395

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:36:26

US3742395

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '08:49'	(b) (4)	20 Jan 2021 17:36:26
	(b) (4), (b) (6)	

US3742395

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '20 Jan 2021 08:49'	System	20 Jan 2021 17:36:26

US3742395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:36:41
	(b) (4), (b) (6)	

US3742395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '20 Jan 2021'	(b) (4)	20 Jan 2021 17:36:41
	(b) (4), (b) (6)	

US3742395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '08:52'	(b) (4)	20 Jan 2021 17:36:41
	(b) (4), (b) (6)	

US3742395

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:21:23

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '20 Jan 2021 08:52'	System	20 Jan 2021 17:36:41

US3742395

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

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:37:27

US3742395

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

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '1'	System	20 Jan 2021 17:37:27

US3742395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4)	27 Jan 2021 21:50:25
	(b) (4), (b) (6)	

US3742395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:50:25

US3742395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:50:25

US3742395

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4)	27 Jan 2021 21:50:25
	(b) (4), (b) (6)	

US3742395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:50:31

US3742395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:44
User entered 'I'	System	27 Jan 2021 21:50:31

US3742395

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:51:44
User entered '1'	System	27 Jan 2021 21:50:31
DataPoint set to visible.	System	27 Jan 2021 21:50:31

US3742395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:44:09

US3742395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '17 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:44:09

US3742395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[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 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	19 Feb 2021 16:44:09

US3742395

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'OLD29'	System	19 Feb 2021 16:44:09

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15
	(b) (4)	

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '17 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '08:57'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '17 Feb 2021 08:57'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '098.8' F	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Oral (Oral)'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '062'	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'bpm'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '16'	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'breaths/min'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '105'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '069'	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15
	(b) (4)	

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '17 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '09:37'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '17 Feb 2021 09:37'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '097.6' F	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Other (Other)'	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'temporal'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '061'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'bpm'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '16'	Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'breaths/min'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '108'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '066'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mmHg'	System	19 Feb 2021 16:48:15

US3742395

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:45:05

US3742395

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '17 Feb 2021'	(b) (4) Sherry McCammon (b) (4)	19 Feb 2021 16:45:05

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	Sherry McCammon (b) (4)	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

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)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	Sherry McCammon (b) (4)	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'mRNA-1273'	System	19 Feb 2021 16:45:36
DataPoint set to visible.	System	27 Jan 2021 21:50:31

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '17 Feb 2021'	Sherry McCammon (b) (4)	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '09:06'	Sherry McCammon (b) (4)	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered '17 Feb 2021 09:06'	System	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Left Arm (LEFT ARM)'	Sherry McCammon (b) (4)	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'ONCE'	System	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:21:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 16:45:36

US3742395

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Feb 2021 16:44:32

US3742395

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:23:57
User entered 'I'	System	19 Feb 2021 16:44:32

US3742395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Mar 2021 18:22:56

US3742395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered '24 Feb 2021'	Sherry McCammon (b) (4)	22 Mar 2021 18:22:56

US3742395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	22 Mar 2021 18:22:56

US3742395

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:21:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:22:56

US3742395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:58
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Mar 2021 18:23:13

US3742395

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:21:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:58
User entered 'I'	System	22 Mar 2021 18:23:13

US3742395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Mar 2021 18:25:52

US3742395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered '17 Mar 2021'	Sherry McCammon (b) (4)	22 Mar 2021 18:25:52

US3742395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	22 Mar 2021 18:25:52

US3742395

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:21:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User entered 'OLD57'	System	22 Mar 2021 18:25:52

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User entered empty.	System	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User entered empty.	System	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User entered empty.	System	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User entered empty.	System	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User entered empty.	System	22 Mar 2021 18:27:20

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23

US3742395

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:21:23

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23

US3742395

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	22 Mar 2021 18:27:48
	(b) (4)	

US3742395

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:21:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 18:27:48

US3742395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Mar 2021 18:28:42

US3742395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered '17 Mar 2021'	Sherry McCammon (b) (4)	22 Mar 2021 18:28:42

US3742395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User entered '08:10'	(b) (4) Sherry McCammon (b) (4)	22 Mar 2021 18:28:42

US3742395

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:21:23

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:23
User entered '17 Mar 2021 08:10'	System	22 Mar 2021 18:28:42

US3742395

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:21:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:56:39

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:06:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:06:12
	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 12:57:57
User entered 'DEEP VEIN THROMBOSIS'	(b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:57:30
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:54:25
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 13:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 06:42:44
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'Participant denies change as of Feb 17th 2021' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	22 Feb 2021 20:58:09
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 15:00:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:57:30
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 13:54:25
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 13:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 17:37:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:37:32
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	21 Oct 2020 17:37:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 12:57:33
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Oct 2020 16:18:45
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:57:30
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:54:25
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 13:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User closed query 'Per CDM: Please select a the appropriate outcome form the drop down box provided. Outcome should reflect the status of the subject at the start of the event and reviewed and updated at each visit.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:36
' (Site from DM). Query 'Per CDM: Please select a the appropriate outcome form the drop down box provided. Outcome should reflect the status of the subject at the start of the event and reviewed and updated at each visit.	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:01:27
' answered with 'participant is recovering - does not have follow up appointment until Feb 2021' (Site from DM). User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:50:20
User opened query 'Per CDM: Please select a the appropriate outcome form the drop down box provided. Outcome should reflect the status of the subject at the start of the event and reviewed and updated at each visit.	(b) (4), (b) (6)	27 Oct 2020 15:41:55
' (Site from DM). User closed query 'Data is required. Please complete.' (Site from System). Query 'Data is required. Please complete.' answered with 'ONGOING' (Site from System).	(b) (4), (b) (6) Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 13:13:49 21 Oct 2020 17:37:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 12:57:33
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:57:30
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 13:54:25
User entered 'Had follow-up visit in February, Dr. told him this is a chronic condition and he would be taking Eliquis for life.' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 13:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:57:33

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 17:37:32

US3742395

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:21:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 12:57:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:21:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 17:34:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: BIKTARVY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 04:50:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 04:50:42
Data point term sent to Coder	System	17 Sep 2020 17:39:58
User entered 'biktaryv- bictegravir, emtricitabine, and tenofovir'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:39:57

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'human immunodeficiency virus'	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:39:57

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User closed query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not comma (e.g. 5/325). If so please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:48:51
Query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not comma (e.g. 5/325). If so please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 14:17:16
User entered '50/200/25' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	03 Nov 2020 14:16:51
User opened query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not comma (e.g. 5/325). If so please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:11:35
User entered '50, 200, 25'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:39:57

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'once daily (QD)'	(b) (4) Hassan Haji (b) (4) (b) (4)	17 Sep 2020 17:39:57

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'UN UNK 2018'	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	17 Sep 2020 17:39:57
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:39:57

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:39:57

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 17:39:57

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Oct 2020 16:27:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:27:17
Data point term sent to Coder	System	06 Oct 2020 16:24:55
User entered 'ENOXAPARIN'	Sherry McCammon (b) (4) (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'DEEP VEIN THROMBOSIS'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '100'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'twice daily (BID)'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '25 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Hassan Haji (b) (4)	05 Nov 2020 20:21:21
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:43:47
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 16:24:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 16:24:39
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Oct 2020 16:24:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 16:23:55
User entered empty.	Sherry McCammon (b) (4)	06 Oct 2020 16:23:55
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '4 Nov 2020' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	05 Nov 2020 20:21:21
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4) System	08 Oct 2020 18:43:47
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	06 Oct 2020 16:24:39
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User entered '2'	System	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User entered '1'	System	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:05
User entered '804 (804)'	System	06 Oct 2020 16:23:55

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Oct 2020 15:36:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:36:44
Data point term sent to Coder	System	22 Oct 2020 15:35:42
User entered 'influenza vaccine'	Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'influenza prophylaxis'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0.5'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'mL (mL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'once (ONCE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '06 Oct 2020'	(b) (4) Hassan Haji (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered '06 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User entered empty.	System	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User entered empty.	System	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:51:07
User entered empty.	System	22 Oct 2020 15:35:23

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 20:23:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:23:39
Data point term sent to Coder	System	05 Nov 2020 20:23:12
User entered 'Eliquis'	Hassan Haji (b) (4) (b) (4)	05 Nov 2020 20:22:58

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'deep vein thrombosis'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered '5'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'mg (mg)'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'twice daily (BID)'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered '5 Nov 2020'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

US3742395

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	05 Nov 2020 20:22:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 20:22:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:22:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:21:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:22:58

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:21:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	12 Mar 2021 18:44:48
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User closed query 'Per CDM:Date of dose discontinuation does not match any dose dates.Please,review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:16
Query 'Per CDM:Date of dose discontinuation does not match any dose dates.Please,review and update accordingly. ' answered with 'DOSE WITHHELD PRIOR TO SECOND DOSE DUE TO AE' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 14:02:02
User opened query 'Per CDM:Date of dose discontinuation does not match any dose dates.Please,review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:40:30
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:33:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 15:33:12
User entered '07 Oct 2020' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	14 Oct 2020 15:33:12
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 15:28:21
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	14 Oct 2020 15:28:21
User entered '7 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 18:40:57

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 15:33:12
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	14 Oct 2020 15:33:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	14 Oct 2020 15:28:21
User entered 'AE (specify) (ADVERSE EVENT)'	Kaitlin Mason (b) (4)	14 Oct 2020 15:28:21
	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:40:57

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:48:15
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:04:46
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 16:20:48
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 16:18:49
User entered 'AE #1' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 16:18:49
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:18:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 23:54:47
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	19 Nov 2020 16:15:22
User entered 'AE 1' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	19 Nov 2020 16:15:17
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:47:30
User entered 'Discontinuation of treatment - participant will remain in the study' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	14 Oct 2020 15:33:12
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	14 Oct 2020 15:28:21
User entered 'DEEP VEIN THROMBOSIS'	(b) (4), (b) (6)	08 Oct 2020 18:40:57

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User closed query 'Per CDM: Please update Date of study discontinuation/completion. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 09:51:25
Query 'Per CDM: Please update Date of study discontinuation/completion. Thank you' answered with 'participant is still in the study ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Oct 2020 15:32:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 09:49:39
User opened query 'Per CDM: Please update Date of study discontinuation/completion. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:49:36
Query 'Data is required. Please complete.' answered with 'ENTERED IN ERROR' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 18:39:52
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 18:39:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:39:29
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 12:58:47

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User closed query 'Per CDM RQ: Please update Reason for discontinuation. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 09:55:03
Query 'Per CDM RQ: Please update Reason for discontinuation. Thank you.' answered with 'Participant is still in the study ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	14 Oct 2020 15:32:18
User opened query 'Per CDM RQ: Please update Reason for discontinuation. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:50:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 09:49:44
Query 'Data is required. Please complete.' answered with 'ENTERED IN ERROR' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 18:39:54
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 18:39:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 18:39:29
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	07 Oct 2020 12:58:47

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:39:29
User entered 'DEEP VEIN THROMBOSIS'	(b) (4), (b) (6)	07 Oct 2020 12:58:47

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:58:47

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:58:47

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:58:47

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:21:23

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:22
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:14:51
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 12:58:47