

US3622032 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:02:46

All time stamps listed in this document are displayed in GMT

US3622032

Form: Participant Creation

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

[Participant ID](#)

US3622032

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

US3622032

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3622032

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

Were any significant conditions reported?

Yes ☒
No ☐

US3622032

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622032

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	06:45 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 06:45
Height (xxx.x)	64.8 in
Weight (xxx.x)	104 lb
BMI (xxx.x)	17.44991 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622032

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3622032

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Date of assessment (dd MMM yyyy) 17 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

US3622032

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 17 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3622032

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Oct 2020 11:50:51

Generated On: 11 Aug 2021 23:02:46

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

What was the participant's randomization number? 104223

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 ☒

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Height	ND - Not Done
Weight	ND - Not Done

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020
Time of assessment (00:00-23:59)	06:45 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 06:45
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 08:55
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)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3622032

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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.

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020

What was the treatment time? (00:00-23:59) 08:20 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 08:20

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

US3622032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

07:00 (24 HR)

Collection date and time (derived)

17 AUG 2020 07:00

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:10	17 AUG 2020 07:10
Nasopharyngeal Swab 2	No		

US3622032

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 09:00

PC Open Date & Time

17 AUG 2020 08:40

PC Close Date & Time

17 AUG 2020 11:10

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

17 AUG 2020 20:29

PC Open Date & Time

17 AUG 2020 12:05

PC Close Date & Time

18 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 22:33

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 22:04

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 06:00

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 21:16

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 22:46

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 20:58

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 09:01

PC Open Date & Time

17 AUG 2020 08:40

PC Close Date & Time

17 AUG 2020 11:10

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 20:30

PC Open Date & Time

17 AUG 2020 12:05

PC Close Date & Time

18 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 22:33

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 22:04

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

21 AUG 2020 06:01

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 21:17

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 22:46

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

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 AUG 2020 20:58

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 09:01
PC Open Date & Time	17 AUG 2020 08:40
PC Close Date & Time	17 AUG 2020 11:10

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 20:30
PC Open Date & Time	17 AUG 2020 12:05
PC Close Date & Time	18 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

45 of 1943

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 22:34
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

47 of 1943

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:05
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

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 ☒

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 06:01
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 1943

EAB) (1725)

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 21:17
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

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 ☒

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 22:46
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 1943

EAB) (1725)

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 20:58
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3622032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Aug 2020 00:26:21

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Aug 2020 00:26:21

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Sep 2020 16:09:04

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Sep 2020 16:09:04

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments UNABLE TO CONTACT

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

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)	14 SEP 2020
Time of assessment (00:00-23:59)	08:14 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 08:14
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	10:04 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 10:04
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3622032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	14 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

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) 14 SEP 2020

What was the treatment time? (00:00-23:59) 09:33 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 09:33

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

US3622032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

08:23 (24 HR)

Collection date and time (derived)

14 SEP 2020 08:23

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:29	14 SEP 2020 08:29
Nasopharyngeal Swab 2	No		

US3622032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 12:37:41

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

98.8 °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

14 SEP 2020 10:07

PC Open Date & Time

14 SEP 2020 09:53

PC Close Date & Time

14 SEP 2020 12:23

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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 98.2 °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	14 SEP 2020 22:09
PC Open Date & Time	14 SEP 2020 13:18
PC Close Date & Time	15 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:36

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

17 SEP 2020 06:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

17 SEP 2020 23:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

18 SEP 2020 20:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 21:19

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

20 SEP 2020 21:15

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

14 SEP 2020 10:07

PC Open Date & Time

14 SEP 2020 09:53

PC Close Date & Time

14 SEP 2020 12:23

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

14 SEP 2020 22:09

PC Open Date & Time

14 SEP 2020 13:18

PC Close Date & Time

15 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

15 SEP 2020 21:36

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

17 SEP 2020 06:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

17 SEP 2020 23:59

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

18 SEP 2020 20:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

19 SEP 2020 21:22

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

20 SEP 2020 21:15

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 10:08
PC Open Date & Time	14 SEP 2020 09:53
PC Close Date & Time	14 SEP 2020 12:23

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 22:09
PC Open Date & Time	14 SEP 2020 13:18
PC Close Date & Time	15 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

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 ☒

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:36
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

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 ☒

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 06:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

96 of 1943

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 23:59
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 1943

EAB) (1725)

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 20:55
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 1943

EAB) (1725)

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:22
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

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 ☒

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 21:15
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3622032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 11:50:51

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 11:50:51

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 11:50:51

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 11:50:51

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Oct 2020 17:47:26

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Oct 2020 17:47:16

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Oct 2020 19:43:04

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Oct 2020 19:43:04

Generated On: 11 Aug 2021 23:02:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:30 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:30
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Oct 2020 19:43:04

Generated On: 11 Aug 2021 23:02:46

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.

US3622032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Oct 2020 19:43:04

Generated On: 11 Aug 2021 23:02:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 OCT 2020
Collection time (00:00-23:59)	8:40 (24 HR)
Collection date and time (derived)	12 OCT 2020 8:40

US3622032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 19:43:04

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☒

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 OCT 2020 07:56:55

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 20:14:00

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 07:35:06

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 23:29:58
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

25 NOV 2020 02:28:37

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 DEC 2020 06:39:52
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☒

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

09 DEC 2020 06:22:26

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 DEC 2020 15:25:47
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 DEC 2020 00:01:19

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 DEC 2020 06:45:50

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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	07 JAN 2021 12:21:16
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 JAN 2021 19:43:41

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

21 JAN 2021 02:43:29

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 20:28:43

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 FEB 2021 14:10:00

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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	10 FEB 2021 22:19:32
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 <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 FEB 2021 19:27:56
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 21:08:44
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

13 MAR 2021 17:15:01

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

19 MAR 2021 12:05:40

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 12:00:43

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 12:03:22
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 09:06:10

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 05:47:21

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 06:07:21

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 271

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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="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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 376

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 411

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 418

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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="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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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="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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 446

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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°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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

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27 FEB 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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03 APR 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 607

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

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

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

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

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

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

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 712

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 747

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

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

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

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

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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="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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 768

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

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

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

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

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

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

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3622032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:02:46

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		01 MAR 2021 06:33:41

US3622032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 14 Nov 2020 18:53:51

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 14 Nov 2020 18:53:51

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 14:57:04

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 14:57:04

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 13:59:05

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 13:59:05

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 13:59:05

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 13:59:05

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT4

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 18:09:30

Generated On: 11 Aug 2021 23:02:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	08:32 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 08:32
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	92 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

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.

US3622032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

08:50 (24 HR)

Collection date and time (derived)

15 MAR 2021 08:50

US3622032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 02:22:19

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments UNABLE TO CONTACT;
MESSAGES LEFT

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 02:22:19

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622032

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:02:46

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"/>

US3622032

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 23:02:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3622032

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

Form: Visit Date

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

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

Visit date (dd MMM yyyy)	7 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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US3622032

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 13:06:58

Generated On: 11 Aug 2021 23:02:46

Date of updated informed consent (<i>dd MMM yyyy</i>)	7 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>)	7 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

US3622032

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

Height	64.8 in
Weight	103 lb
BMI (xxx.x)	17.28212

US3622032

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

Height	64.8 in
Weight	103 lb
BMI (xxx.x)	17.28212
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)	7 JAN 2021
Time of assessment (00:00-23:59)	12:37 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 12:37
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	97 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)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3622032

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

Height	64.8 in
Weight	103 lb
BMI (xxx.x)	17.28212
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)	7 JAN 2021
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	7 JAN 2021 14:06
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3622032

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

Form: Physical Examination

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

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.

US3622032

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

Form: Pregnancy Test

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	7 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3622032

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

Form: Exposure

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

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) 7 JAN 2021

What was the treatment time? (00:00-23:59) 13:34 (24 HR)

Treatment Date and Time (derived) 7 JAN 2021 13:34

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

US3622032

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 JAN 2021

Collection time (00:00-23:59)

12:59 (24 HR)

Collection date and time (derived)

7 JAN 2021 12:59

US3622032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 JAN 2021
Collection time (00:00 - 23:59)	12:55
Collection Date and Time (derived)	7 JAN 2021 12:55

US3622032

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

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 14:57:03

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Jan 2021 14:47:31

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Jan 2021 14:47:31

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 20:38:11

Generated On: 11 Aug 2021 23:02:46

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	08:28 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 08:28
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	96 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 20:38:11

Generated On: 11 Aug 2021 23:02:46

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	09:27 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 09:27
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3622032

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

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.

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	4 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3622032

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

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) 8 FEB 2021

What was the treatment time? (00:00-23:59) 08:54 (24 HR)

Treatment Date and Time (derived) 8 FEB 2021 08:54

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

US3622032

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:04:18

Generated On: 11 Aug 2021 23:02:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:04:18

Generated On: 11 Aug 2021 23:02:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622032

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:32 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 08:32
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	101 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	92 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622032

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

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.

US3622032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 14:00:51

Generated On: 11 Aug 2021 23:02:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

08:50 (24 HR)

Collection date and time (derived)

15 MAR 2021 08:50

US3622032

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Jan 2021 14:47:30

Generated On: 11 Aug 2021 23:02:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

AEID

Adverse event

LEFT ARM INJECTION SITE

PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

7 JAN 2021

Start time (00:00-23:59)

16:00 (24 HR)

AE start date and time (derived)

7 JAN 2021 16:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

9 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

346 of 1943

EAB) (1725)

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

AEID	USA-US085-2021-MRNA-1273-P30 1000011
Adverse event	PREGNANCY
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)	18 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 1943

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Aug 2020 17:52:05

Generated On: 11 Aug 2021 23:02:46

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

Yes ☒

No ☐

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

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

Name of Medication	PROGESTIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	BIRTH CONTROL
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 1943

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

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

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication VITAMIN SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

353 of 1943

EAB) (1725)

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

	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 SEP 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT ARM INJECTION SITE
PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

355 of 1943

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

	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)		7 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

Name of Medication PRENATAL VITAMIN (ALIVE)

Prophylaxis Yes ☒
No ☐

Indication PREGNANCY SUPPLEMENT

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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)

357 of 1943

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
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"/>

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

359 of 1943

EAB) (1725)

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 19:53:23

Generated On: 11 Aug 2021 23:02:46

	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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3622032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3622032

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:02:46

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 ☐

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

SAEID	USA-US085-2021-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 13:59:04

Generated On: 11 Aug 2021 23:02:46

SAEID	USA-US085-2021-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	08/FEB/2021 18:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3622032 (Prod: University of Miami)

US3622032

Form: Participant Creation

Generated On: 11 Aug 2021 23:02:46

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'US3622032'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 11:44:24

US3622032

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:50:40

US3622032

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 11:44:25

US3622032

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:50:40

US3622032

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'SCRN'	System	17 Aug 2020 11:50:40

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered (b) (6) 1987'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 11:44:26

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '33'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'YEARS'	System	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '33'	System	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'I'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:02:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 15:58:11

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'Aug 2020'	System	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '2020'	System	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:16

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 11:44:25

US3622032

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:02:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'I'	System	17 Aug 2020 11:51:21

US3622032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:21

US3622032

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 23:02:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
Signature has been broken.	(b) (4)	15 Mar 2021 13:32:12
User entered 'Yes (Y)' reason for change: New Information	Junlin Long (b) (4)	15 Mar 2021 13:32:12
User closed query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify.'	(b) (4)	23 Dec 2020 03:29:50
(Site from DM).		
Query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify.'	Junlin Long (b) (4)	22 Dec 2020 13:30:42
' answered with 'confirmed that participant did not report any clinically significant mh.' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify.'	(b) (4), (b) (6)	22 Dec 2020 11:10:17
(Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4)	18 Aug 2020 15:58:29
	(b) (4), (b) (6)	

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 13:48:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 13:48:56
Data point term sent to Coder	System	15 Mar 2021 13:33:14
User entered 'seasonal allergies'	Junlin Long (b) (4)	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'un UNK 2003'	Junlin Long	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '0'	Junlin Long	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Yes (Y)'	Junlin Long	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered empty.	Junlin Long	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '0'	Junlin Long	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'Jan 2003'	System	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '2003'	System	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered empty.	System	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered empty.	System	15 Mar 2021 13:32:32

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '06:45'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '17 Aug 2020 06:45'	System	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '64.8' in	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:01
DataPoint set to visible.	System	17 Aug 2020 11:51:21

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '104' lb	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:01
DataPoint set to visible.	System	17 Aug 2020 11:51:21

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
Amendment Manager: User entered '17.44991'	System	16 Sep 2020 23:59:14
User closed query 'Per CDM: Please confirm if Height and Weight values are normal, as BMI suggests patient is underweight. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 05:12:12
Query 'Per CDM: Please confirm if Height and Weight values are normal, as BMI suggests patient is underweight. Thank you' answered with 'Values confirmed.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:28:40
User opened query 'Per CDM: Please confirm if Height and Weight values are normal, as BMI suggests patient is underweight. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 18:17:38
User entered '17.4'	System	18 Aug 2020 16:01:01
DataPoint set to visible.	System	17 Aug 2020 11:51:21

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'kg/m2'	System	18 Aug 2020 16:01:01
DataPoint set to visible.	System	17 Aug 2020 11:51:21

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'bpm'	System	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'breaths/min'	System	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'mmHg'	System	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'mmHg'	System	18 Aug 2020 16:01:01

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30

US3622032

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30

US3622032

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:12

US3622032

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 11:50:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:49:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:12

US3622032

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:02:46

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:32

US3622032

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:32

US3622032

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:32

US3622032

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:32

US3622032

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:32

US3622032

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:02:46

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:32

US3622032

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:32

US3622032

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:02:46

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:01:32

US3622032

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:00

US3622032

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 16:02:00

US3622032

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:00

US3622032

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:00

US3622032

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:00

US3622032

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:02:00

US3622032

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:02:00

US3622032

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered empty.	System	18 Aug 2020 16:02:00

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:02:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:31

US3622032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:32

US3622032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:32

US3622032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 11:51:32

US3622032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'VISIT1'	System	17 Aug 2020 11:51:32

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 11:44:27

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 04:55:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:55:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 11:44:27
User entered '104223' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 11:44:27

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 11:44:27

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

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)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:58

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

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)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:58

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:58

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:58

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:02:58

US3622032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:02:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered 'No (N)'	Junlin Long	29 Sep 2020 13:23:10
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:34:24

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '06:45'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '17 Aug 2020 06:45'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '98.1' F	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '78'	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'bpm'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'breaths/min'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '101'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '69'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:28:23
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 16:05:45
User entered '08:55'	(b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '17 Aug 2020 08:55'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '85'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'bpm'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'breaths/min'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '90'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '60'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	18 Aug 2020 16:05:45

US3622032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:05:50

US3622032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:05:50

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
User closed query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 04:37:30
Query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.'	(b) (4), (b) (6)	10 Sep 2020 12:51:36
answered with 'changed to no; this was not on the eCRF completion guidelines' (Site from DM).		
Signature has been broken.	(b) (4), (b) (6)	10 Sep 2020 12:51:32
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:51:32
User opened query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 09:16:50
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:06:39

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:51:32
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:51:32
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:06:39

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:51:32
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:51:32
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:06:39

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:51:32
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:51:32
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:06:39

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:44:02
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you ' answered with 'FSH marked no' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:12:12
Signature has been broken.	(b) (4), (b) (6)	16 Sep 2020 16:12:05
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Sep 2020 16:12:05
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 11:37:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 12:51:32
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	10 Sep 2020 12:51:32
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:06:39

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:06:39

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:06:39

US3622032

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered empty.	System	18 Aug 2020 16:06:39

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '08:20'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '17 Aug 2020 08:20'	System	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'ONCE'	System	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 12:53:54

US3622032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:06:51

US3622032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 16:06:51

US3622032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '07:00'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:06:51

US3622032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '17 Aug 2020 07:00'	System	18 Aug 2020 16:06:51

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '07:10'	(b) (4), (b) (6)	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '17 Aug 2020 07:10'	System	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:46

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered empty.	System	18 Aug 2020 16:07:03

US3622032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:07:09

US3622032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'I'	System	18 Aug 2020 16:07:09

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:00:36', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '199e46a2-8fb1-4aad-ae67-c594400b51ef' User entered 'Yes (Y)'	System	17 Aug 2020 13:00:54
	System	17 Aug 2020 13:00:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:00:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '199e46a2-8fb1-4aad-ae67-c594400b51ef' User entered '98.4'	System	17 Aug 2020 13:00:54
	System	17 Aug 2020 13:00:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:00:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '199e46a2-8fb1-4aad-ae67-c594400b51ef'	System	17 Aug 2020 13:00:54
User entered 'No (N)'	System	17 Aug 2020 13:00:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:00:50', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '199e46a2-8fb1-4aad-ae67-c594400b51ef' User entered '17 Aug 2020 09:00'	System	17 Aug 2020 13:00:54
	System	17 Aug 2020 13:00:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 08:40'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 11:10'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:29:24', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '1c4bcbd8-d0ca-47aa-93d2-a248a46c85e9' User entered 'Yes (Y)'	System	18 Aug 2020 00:30:07
	System	18 Aug 2020 00:30:07

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:29:28', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '1c4bcbd8-d0ca-47aa-93d2-a248a46c85e9' User entered '97.2'	System	18 Aug 2020 00:30:07
	System	18 Aug 2020 00:30:07

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:29:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '1c4bcbd8-d0ca-47aa-93d2-a248a46c85e9'	System	18 Aug 2020 00:30:07
User entered 'No (N)'	System	18 Aug 2020 00:30:07

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:29:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '1c4bcbd8-d0ca-47aa-93d2-a248a46c85e9' User entered '17 Aug 2020 20:29'	System	18 Aug 2020 00:30:07
	System	18 Aug 2020 00:30:07

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 2'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '9ab4267d-5b33-4891-a14e-d4431d670689' User entered 'Yes (Y)'	System	19 Aug 2020 02:33:42
	System	19 Aug 2020 02:33:42

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:30', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '9ab4267d-5b33-4891-a14e-d4431d670689' User entered '96.6'	System	19 Aug 2020 02:33:42
	System	19 Aug 2020 02:33:42

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '9ab4267d-5b33-4891-a14e-d4431d670689' User entered 'No (N)'	System	19 Aug 2020 02:33:42
	System	19 Aug 2020 02:33:42

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:38', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '9ab4267d-5b33-4891-a14e-d4431d670689' User entered '18 Aug 2020 22:33'	System	19 Aug 2020 02:33:42
	System	19 Aug 2020 02:33:42

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 3'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:34', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b5458b21-4d25-4e9b-8c39-60e4ed6ff695'	System	20 Aug 2020 02:04:46
User entered 'Yes (Y)'	System	20 Aug 2020 02:04:46

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:38', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b5458b21-4d25-4e9b-8c39-60e4ed6ff695' User entered '98.0'	System	20 Aug 2020 02:04:46
	System	20 Aug 2020 02:04:46

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b5458b21-4d25-4e9b-8c39-60e4ed6ff695'	System	20 Aug 2020 02:04:46
User entered 'No (N)'	System	20 Aug 2020 02:04:46

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b5458b21-4d25-4e9b-8c39-60e4ed6ff695'	System	20 Aug 2020 02:04:46
User entered '19 Aug 2020 22:04'	System	20 Aug 2020 02:04:46

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 4'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:00:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '49813227-f7e1-4979-bbb1-166d43457ab3' User entered 'Yes (Y)'	System	21 Aug 2020 10:00:48
	System	21 Aug 2020 10:00:48

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:00:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '49813227-f7e1-4979-bbb1-166d43457ab3' User entered '98.2'	System	21 Aug 2020 10:00:48
	System	21 Aug 2020 10:00:48

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:00:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '49813227-f7e1-4979-bbb1-166d43457ab3'	System	21 Aug 2020 10:00:48
User entered 'No (N)'	System	21 Aug 2020 10:00:48

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:00:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '49813227-f7e1-4979-bbb1-166d43457ab3'	System	21 Aug 2020 10:00:48
User entered '21 Aug 2020 06:00'	System	21 Aug 2020 10:00:48

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 5'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:16:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd9eb9272-da46-47c4-b1ed-1fb7cbcf5c59'	System	22 Aug 2020 01:16:53
User entered 'Yes (Y)'	System	22 Aug 2020 01:16:53

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:16:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd9eb9272-da46-47c4-b1ed-1fb7cbcf5c59' User entered '98.1'	System	22 Aug 2020 01:16:53
	System	22 Aug 2020 01:16:53

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:16:48', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd9eb9272-da46-47c4-b1ed-1fb7cbcf5c59'	System	22 Aug 2020 01:16:53
User entered 'No (N)'	System	22 Aug 2020 01:16:53

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:16:50', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd9eb9272-da46-47c4-b1ed-1fb7cbcf5c59'	System	22 Aug 2020 01:16:53
User entered '21 Aug 2020 21:16'	System	22 Aug 2020 01:16:53

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 6'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:02', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '42a43a28-5fb3-470e-98f1-9ed7101dfdb0' User entered 'Yes (Y)'	System	23 Aug 2020 02:46:14
	System	23 Aug 2020 02:46:14

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:07', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '42a43a28-5fb3-470e-98f1-9ed7101dfdb0' User entered '97.0'	System	23 Aug 2020 02:46:14
	System	23 Aug 2020 02:46:14

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:10', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '42a43a28-5fb3-470e-98f1-9ed7101dfdb0'	System	23 Aug 2020 02:46:14
User entered 'No (N)'	System	23 Aug 2020 02:46:14

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:13', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '42a43a28-5fb3-470e-98f1-9ed7101dfdb0' User entered '22 Aug 2020 22:46'	System	23 Aug 2020 02:46:14
	System	23 Aug 2020 02:46:14

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 7'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:14', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '532ee20c-fdb2-4053-87e5-93f87ecddb42'	System	24 Aug 2020 00:58:28
User entered 'Yes (Y)'	System	24 Aug 2020 00:58:28

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:21', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '532ee20c-fdb2-4053-87e5-93f87ecddb42' User entered '98.3'	System	24 Aug 2020 00:58:28
	System	24 Aug 2020 00:58:28

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:23', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '532ee20c-fdb2-4053-87e5-93f87ecddb42'	System	24 Aug 2020 00:58:28
User entered 'No (N)'	System	24 Aug 2020 00:58:28

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '532ee20c-fdb2-4053-87e5-93f87ecddb42' User entered '23 Aug 2020 20:58'	System	24 Aug 2020 00:58:28
	System	24 Aug 2020 00:58:28

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:00:58', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'daf8de51-173b-4eef-a0fa-13576868e215'	System	17 Aug 2020 13:01:29
User entered 'None (1)'	System	17 Aug 2020 13:01:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:08', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'daf8de51-173b-4eef-a0fa-13576868e215'	System	17 Aug 2020 13:01:29
User entered 'No (N)'	System	17 Aug 2020 13:01:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:16', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'daf8de51-173b-4eef-a0fa-13576868e215'	System	17 Aug 2020 13:01:29
User entered 'No (N)'	System	17 Aug 2020 13:01:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:23', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'daf8de51-173b-4eef-a0fa-13576868e215' User entered 'None (1)'	System	17 Aug 2020 13:01:29
	System	17 Aug 2020 13:01:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'daf8de51-173b-4eef-a0fa-13576868e215' User entered '17 Aug 2020 09:01'	System	17 Aug 2020 13:01:29
	System	17 Aug 2020 13:01:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 08:40'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 11:10'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:29:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '68b74ad8-f20e-48f9-a394-df0386a12c68' User entered 'None (1)'	System	18 Aug 2020 00:30:16
	System	18 Aug 2020 00:30:16

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:29:57', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '68b74ad8-f20e-48f9-a394-df0386a12c68' User entered 'No (N)'	System	18 Aug 2020 00:30:16
	System	18 Aug 2020 00:30:16

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:04', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '68b74ad8-f20e-48f9-a394-df0386a12c68'	System	18 Aug 2020 00:30:16
User entered 'No (N)'	System	18 Aug 2020 00:30:16

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:11', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '68b74ad8-f20e-48f9-a394-df0386a12c68' User entered 'None (1)'	System	18 Aug 2020 00:30:16
	System	18 Aug 2020 00:30:16

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:14', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '68b74ad8-f20e-48f9-a394-df0386a12c68'	System	18 Aug 2020 00:30:16
User entered '17 Aug 2020 20:30'	System	18 Aug 2020 00:30:16

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 2'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '92a31e6a-7a30-4b01-a45b-f6a7e0c459cb' User entered 'None (1)'	System	19 Aug 2020 02:34:00
	System	19 Aug 2020 02:34:00

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '92a31e6a-7a30-4b01-a45b-f6a7e0c459cb' User entered 'No (N)'	System	19 Aug 2020 02:34:00
	System	19 Aug 2020 02:34:00

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '92a31e6a-7a30-4b01-a45b-f6a7e0c459cb' User entered 'No (N)'	System	19 Aug 2020 02:34:00
	System	19 Aug 2020 02:34:00

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:53', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '92a31e6a-7a30-4b01-a45b-f6a7e0c459cb' User entered 'None (1)'	System	19 Aug 2020 02:34:00
	System	19 Aug 2020 02:34:00

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:33:55', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '92a31e6a-7a30-4b01-a45b-f6a7e0c459cb' User entered '18 Aug 2020 22:33'	System	19 Aug 2020 02:34:00
	System	19 Aug 2020 02:34:00

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 3'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dcad2e74-398e-4db2-8e81-bec265254244'	System	20 Aug 2020 02:05:01
User entered 'None (1)'	System	20 Aug 2020 02:05:01

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:50', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dcad2e74-398e-4db2-8e81-bec265254244'	System	20 Aug 2020 02:05:01
User entered 'No (N)'	System	20 Aug 2020 02:05:01

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:52', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dcad2e74-398e-4db2-8e81-bec265254244' User entered 'No (N)'	System	20 Aug 2020 02:05:01
	System	20 Aug 2020 02:05:01

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:55', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dcad2e74-398e-4db2-8e81-bec265254244'	System	20 Aug 2020 02:05:01
User entered 'None (1)'	System	20 Aug 2020 02:05:01

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:04:58', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dcad2e74-398e-4db2-8e81-bec265254244' User entered '19 Aug 2020 22:04'	System	20 Aug 2020 02:05:01
	System	20 Aug 2020 02:05:01

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 4'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:00:53', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6412ab6d-9cae-4135-a88f-621502a284fe' User entered 'None (1)'	System	21 Aug 2020 10:01:13
	System	21 Aug 2020 10:01:13

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:00:56', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6412ab6d-9cae-4135-a88f-621502a284fe' User entered 'No (N)'	System	21 Aug 2020 10:01:13
	System	21 Aug 2020 10:01:13

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:00:59', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6412ab6d-9cae-4135-a88f-621502a284fe' User entered 'No (N)'	System	21 Aug 2020 10:01:13
	System	21 Aug 2020 10:01:13

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:07', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6412ab6d-9cae-4135-a88f-621502a284fe' User entered 'None (1)'	System	21 Aug 2020 10:01:13
	System	21 Aug 2020 10:01:13

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:11', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6412ab6d-9cae-4135-a88f-621502a284fe' User entered '21 Aug 2020 06:01'	System	21 Aug 2020 10:01:13
	System	21 Aug 2020 10:01:13

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 5'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:16:54', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6031bcee-554c-4ed7-9e6a-9a3f567b2eb4' User entered 'None (1)'	System	22 Aug 2020 01:17:27
	System	22 Aug 2020 01:17:27

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:14', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6031bcee-554c-4ed7-9e6a-9a3f567b2eb4' User entered 'No (N)'	System	22 Aug 2020 01:17:27
	System	22 Aug 2020 01:17:27

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:17', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6031bcee-554c-4ed7-9e6a-9a3f567b2eb4' User entered 'No (N)'	System	22 Aug 2020 01:17:27
	System	22 Aug 2020 01:17:27

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:20', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6031bcee-554c-4ed7-9e6a-9a3f567b2eb4' User entered 'None (1)'	System	22 Aug 2020 01:17:27
	System	22 Aug 2020 01:17:27

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:25', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6031bcee-554c-4ed7-9e6a-9a3f567b2eb4' User entered '21 Aug 2020 21:17'	System	22 Aug 2020 01:17:27
	System	22 Aug 2020 01:17:27

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 6'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:17', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6c437cc1-bec1-4fad-8d74-845c4ff21f1f' User entered 'None (1)'	System	23 Aug 2020 02:46:29
	System	23 Aug 2020 02:46:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:20', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6c437cc1-bec1-4fad-8d74-845c4ff21f1f' User entered 'No (N)'	System	23 Aug 2020 02:46:29
	System	23 Aug 2020 02:46:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:22', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6c437cc1-bec1-4fad-8d74-845c4ff21f1f' User entered 'No (N)'	System	23 Aug 2020 02:46:29
	System	23 Aug 2020 02:46:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:23', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6c437cc1-bec1-4fad-8d74-845c4ff21f1f' User entered 'None (1)'	System	23 Aug 2020 02:46:29
	System	23 Aug 2020 02:46:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '6c437cc1-bec1-4fad-8d74-845c4ff21f1f' User entered '22 Aug 2020 22:46'	System	23 Aug 2020 02:46:29
	System	23 Aug 2020 02:46:29

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 7'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '7f6a478b-fbe3-4acc-82f2-6bddd8a2fba1' User entered 'None (1)'	System	24 Aug 2020 00:58:39
	System	24 Aug 2020 00:58:39

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:32', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '7f6a478b-fbe3-4acc-82f2-6bddd8a2fba1' User entered 'No (N)'	System	24 Aug 2020 00:58:39
	System	24 Aug 2020 00:58:39

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:33', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '7f6a478b-fbe3-4acc-82f2-6bddd8a2fba1' User entered 'No (N)'	System	24 Aug 2020 00:58:39
	System	24 Aug 2020 00:58:39

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '7f6a478b-fbe3-4acc-82f2-6bddd8a2fba1' User entered 'None (1)'	System	24 Aug 2020 00:58:39
	System	24 Aug 2020 00:58:39

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:37', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '7f6a478b-fbe3-4acc-82f2-6bddd8a2fba1' User entered '23 Aug 2020 20:58'	System	24 Aug 2020 00:58:39
	System	24 Aug 2020 00:58:39

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:33', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '090a2d35-f1b4-45e3-a0e2-e182b45d9988' User entered 'None (0)'	System	17 Aug 2020 13:01:58
	System	17 Aug 2020 13:01:58

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:42', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '090a2d35-f1b4-45e3-a0e2-e182b45d9988' User entered 'None (0)'	System	17 Aug 2020 13:01:58
	System	17 Aug 2020 13:01:58

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:44', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '090a2d35-f1b4-45e3-a0e2-e182b45d9988' User entered 'None (0)'	System	17 Aug 2020 13:01:58
	System	17 Aug 2020 13:01:58

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '090a2d35-f1b4-45e3-a0e2-e182b45d9988' User entered 'None (0)'	System	17 Aug 2020 13:01:58
	System	17 Aug 2020 13:01:58

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:49', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '090a2d35-f1b4-45e3-a0e2-e182b45d9988' User entered 'None (0)'	System	17 Aug 2020 13:01:58
	System	17 Aug 2020 13:01:58

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:51', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '090a2d35-f1b4-45e3-a0e2-e182b45d9988' User entered 'None (0)'	System	17 Aug 2020 13:01:58
	System	17 Aug 2020 13:01:58

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:55', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '090a2d35-f1b4-45e3-a0e2-e182b45d9988'	System	17 Aug 2020 13:01:58
User entered 'No (N)'	System	17 Aug 2020 13:01:58

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T09:01:57', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '090a2d35-f1b4-45e3-a0e2-e182b45d9988'	System	17 Aug 2020 13:01:58
User entered '17 Aug 2020 09:01'	System	17 Aug 2020 13:01:58

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 08:40'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 11:10'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:17', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '971d1cbe-1eb5-477c-ad47-d1ac00a521d7' User entered 'None (0)'	System	18 Aug 2020 00:30:53
	System	18 Aug 2020 00:30:53

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:19', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '971d1cbe-1eb5-477c-ad47-d1ac00a521d7' User entered 'None (0)'	System	18 Aug 2020 00:30:53
	System	18 Aug 2020 00:30:53

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:21', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '971d1cbe-1eb5-477c-ad47-d1ac00a521d7' User entered 'None (0)'	System	18 Aug 2020 00:30:53
	System	18 Aug 2020 00:30:53

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:23', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '971d1cbe-1eb5-477c-ad47-d1ac00a521d7' User entered 'None (0)'	System	18 Aug 2020 00:30:53
	System	18 Aug 2020 00:30:53

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:24', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '971d1cbe-1eb5-477c-ad47-d1ac00a521d7' User entered 'None (0)'	System	18 Aug 2020 00:30:53
	System	18 Aug 2020 00:30:53

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '971d1cbe-1eb5-477c-ad47-d1ac00a521d7' User entered 'None (0)'	System	18 Aug 2020 00:30:53
	System	18 Aug 2020 00:30:53

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '971d1cbe-1eb5-477c-ad47-d1ac00a521d7' User entered 'No (N)'	System	18 Aug 2020 00:30:53
	System	18 Aug 2020 00:30:53

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-17T20:30:49', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '971d1cbe-1eb5-477c-ad47-d1ac00a521d7' User entered '17 Aug 2020 20:30'	System	18 Aug 2020 00:30:53
	System	18 Aug 2020 00:30:53

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Aug 2020 12:05'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 2'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:34:17', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c9493b17-2643-4c16-8248-4df6e5e0bd0b' User entered 'None (0)'	System	19 Aug 2020 02:34:35
	System	19 Aug 2020 02:34:35

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:34:20', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c9493b17-2643-4c16-8248-4df6e5e0bd0b' User entered 'None (0)'	System	19 Aug 2020 02:34:35
	System	19 Aug 2020 02:34:35

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:34:22', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c9493b17-2643-4c16-8248-4df6e5e0bd0b' User entered 'None (0)'	System	19 Aug 2020 02:34:35
	System	19 Aug 2020 02:34:35

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:34:24', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c9493b17-2643-4c16-8248-4df6e5e0bd0b' User entered 'None (0)'	System	19 Aug 2020 02:34:35
	System	19 Aug 2020 02:34:35

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:34:25', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c9493b17-2643-4c16-8248-4df6e5e0bd0b' User entered 'None (0)'	System	19 Aug 2020 02:34:35
	System	19 Aug 2020 02:34:35

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:34:27', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c9493b17-2643-4c16-8248-4df6e5e0bd0b' User entered 'None (0)'	System	19 Aug 2020 02:34:35
	System	19 Aug 2020 02:34:35

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:34:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c9493b17-2643-4c16-8248-4df6e5e0bd0b' User entered 'No (N)'	System	19 Aug 2020 02:34:35
	System	19 Aug 2020 02:34:35

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-18T22:34:34', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c9493b17-2643-4c16-8248-4df6e5e0bd0b' User entered '18 Aug 2020 22:34'	System	19 Aug 2020 02:34:35
	System	19 Aug 2020 02:34:35

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 3'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:05:02', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd6df03e6-75c4-4fa9-a93b-ffa0a1266ba2' User entered 'None (0)'	System	20 Aug 2020 02:05:28
	System	20 Aug 2020 02:05:28

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:05:04', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd6df03e6-75c4-4fa9-a93b-ffa0a1266ba2' User entered 'None (0)'	System	20 Aug 2020 02:05:28
	System	20 Aug 2020 02:05:28

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:05:06', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd6df03e6-75c4-4fa9-a93b-ffa0a1266ba2' User entered 'None (0)'	System	20 Aug 2020 02:05:28
	System	20 Aug 2020 02:05:28

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:05:07', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd6df03e6-75c4-4fa9-a93b-ffa0a1266ba2' User entered 'None (0)'	System	20 Aug 2020 02:05:28
	System	20 Aug 2020 02:05:28

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:05:09', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd6df03e6-75c4-4fa9-a93b-ffa0a1266ba2' User entered 'None (0)'	System	20 Aug 2020 02:05:28
	System	20 Aug 2020 02:05:28

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:05:10', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd6df03e6-75c4-4fa9-a93b-ffa0a1266ba2' User entered 'None (0)'	System	20 Aug 2020 02:05:28
	System	20 Aug 2020 02:05:28

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:05:22', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd6df03e6-75c4-4fa9-a93b-ffa0a1266ba2' User entered 'No (N)'	System	20 Aug 2020 02:05:28
	System	20 Aug 2020 02:05:28

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-19T22:05:25', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'd6df03e6-75c4-4fa9-a93b-ffa0a1266ba2' User entered '19 Aug 2020 22:05'	System	20 Aug 2020 02:05:28
	System	20 Aug 2020 02:05:28

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 4'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:15', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf8294d8-a8c2-4761-8ad1-cd4bb361b1dd' User entered 'None (0)'	System	21 Aug 2020 10:01:40
	System	21 Aug 2020 10:01:40

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:19', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf8294d8-a8c2-4761-8ad1-cd4bb361b1dd' User entered 'None (0)'	System	21 Aug 2020 10:01:40
	System	21 Aug 2020 10:01:40

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:22', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf8294d8-a8c2-4761-8ad1-cd4bb361b1dd' User entered 'None (0)'	System	21 Aug 2020 10:01:40
	System	21 Aug 2020 10:01:40

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:27', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf8294d8-a8c2-4761-8ad1-cd4bb361b1dd' User entered 'None (0)'	System	21 Aug 2020 10:01:40
	System	21 Aug 2020 10:01:40

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf8294d8-a8c2-4761-8ad1-cd4bb361b1dd' User entered 'None (0)'	System	21 Aug 2020 10:01:40
	System	21 Aug 2020 10:01:40

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf8294d8-a8c2-4761-8ad1-cd4bb361b1dd' User entered 'None (0)'	System	21 Aug 2020 10:01:40
	System	21 Aug 2020 10:01:40

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf8294d8-a8c2-4761-8ad1-cd4bb361b1dd' User entered 'No (N)'	System	21 Aug 2020 10:01:40
	System	21 Aug 2020 10:01:40

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T06:01:38', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf8294d8-a8c2-4761-8ad1-cd4bb361b1dd' User entered '21 Aug 2020 06:01'	System	21 Aug 2020 10:01:40
	System	21 Aug 2020 10:01:40

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 5'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3b5cf99a-c997-4ab8-8d53-30ad3f0ed423' User entered 'None (0)'	System	22 Aug 2020 01:17:50
	System	22 Aug 2020 01:17:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3b5cf99a-c997-4ab8-8d53-30ad3f0ed423' User entered 'None (0)'	System	22 Aug 2020 01:17:50
	System	22 Aug 2020 01:17:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:33', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3b5cf99a-c997-4ab8-8d53-30ad3f0ed423' User entered 'None (0)'	System	22 Aug 2020 01:17:50
	System	22 Aug 2020 01:17:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3b5cf99a-c997-4ab8-8d53-30ad3f0ed423' User entered 'None (0)'	System	22 Aug 2020 01:17:50
	System	22 Aug 2020 01:17:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:36', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3b5cf99a-c997-4ab8-8d53-30ad3f0ed423' User entered 'None (0)'	System	22 Aug 2020 01:17:50
	System	22 Aug 2020 01:17:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:38', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3b5cf99a-c997-4ab8-8d53-30ad3f0ed423' User entered 'None (0)'	System	22 Aug 2020 01:17:50
	System	22 Aug 2020 01:17:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:44', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3b5cf99a-c997-4ab8-8d53-30ad3f0ed423'	System	22 Aug 2020 01:17:50
User entered 'No (N)'	System	22 Aug 2020 01:17:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-21T21:17:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3b5cf99a-c997-4ab8-8d53-30ad3f0ed423' User entered '21 Aug 2020 21:17'	System	22 Aug 2020 01:17:50
	System	22 Aug 2020 01:17:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 6'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:30', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '415e6100-47c1-402c-99d4-6b6cf981c685' User entered 'None (0)'	System	23 Aug 2020 02:46:49
	System	23 Aug 2020 02:46:49

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:33', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '415e6100-47c1-402c-99d4-6b6cf981c685' User entered 'None (0)'	System	23 Aug 2020 02:46:49
	System	23 Aug 2020 02:46:49

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '415e6100-47c1-402c-99d4-6b6cf981c685' User entered 'None (0)'	System	23 Aug 2020 02:46:49
	System	23 Aug 2020 02:46:49

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:37', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '415e6100-47c1-402c-99d4-6b6cf981c685' User entered 'None (0)'	System	23 Aug 2020 02:46:49
	System	23 Aug 2020 02:46:49

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:39', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '415e6100-47c1-402c-99d4-6b6cf981c685' User entered 'None (0)'	System	23 Aug 2020 02:46:49
	System	23 Aug 2020 02:46:49

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '415e6100-47c1-402c-99d4-6b6cf981c685' User entered 'None (0)'	System	23 Aug 2020 02:46:49
	System	23 Aug 2020 02:46:49

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '415e6100-47c1-402c-99d4-6b6cf981c685'	System	23 Aug 2020 02:46:49
User entered 'No (N)'	System	23 Aug 2020 02:46:49

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-22T22:46:48', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '415e6100-47c1-402c-99d4-6b6cf981c685' User entered '22 Aug 2020 22:46'	System	23 Aug 2020 02:46:49
	System	23 Aug 2020 02:46:49

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 7'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '945faedd-c8c1-482f-acb7-d41bd6ee97be' User entered 'None (0)'	System	24 Aug 2020 00:59:50
	System	24 Aug 2020 00:59:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '945faedd-c8c1-482f-acb7-d41bd6ee97be' User entered 'None (0)'	System	24 Aug 2020 00:59:50
	System	24 Aug 2020 00:59:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '945faedd-c8c1-482f-acb7-d41bd6ee97be' User entered 'None (0)'	System	24 Aug 2020 00:59:50
	System	24 Aug 2020 00:59:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:48', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '945faedd-c8c1-482f-acb7-d41bd6ee97be' User entered 'None (0)'	System	24 Aug 2020 00:59:50
	System	24 Aug 2020 00:59:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:49', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '945faedd-c8c1-482f-acb7-d41bd6ee97be' User entered 'None (0)'	System	24 Aug 2020 00:59:50
	System	24 Aug 2020 00:59:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:51', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '945faedd-c8c1-482f-acb7-d41bd6ee97be' User entered 'None (0)'	System	24 Aug 2020 00:59:50
	System	24 Aug 2020 00:59:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:55', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '945faedd-c8c1-482f-acb7-d41bd6ee97be' User entered 'No (N)'	System	24 Aug 2020 00:59:50
	System	24 Aug 2020 00:59:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-08-23T20:58:57', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '945faedd-c8c1-482f-acb7-d41bd6ee97be' User entered '23 Aug 2020 20:58'	System	24 Aug 2020 00:59:50
	System	24 Aug 2020 00:59:50

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 12:53:54

US3622032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Aug 2020 00:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 13:34:51

US3622032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Aug 2020 00:26:21
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 13:34:51

US3622032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Aug 2020 00:26:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 13:34:51

US3622032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Aug 2020 00:26:21
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 13:34:51

US3622032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Aug 2020 00:26:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 13:34:57

US3622032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'I'	System	25 Aug 2020 13:34:57

US3622032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:30:45

US3622032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
User entered '1 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 12:30:45

US3622032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:30:45

US3622032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:30:45

US3622032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:09:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:30:50

US3622032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'I'	System	03 Sep 2020 12:30:50

US3622032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:49:12

US3622032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '7 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 13:49:12

US3622032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	14 Sep 2020 13:49:12

US3622032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'unable to contact'	(b) (4), (b) (6)	14 Sep 2020 13:49:12

US3622032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:49:16

US3622032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'I'	System	14 Sep 2020 13:49:16

US3622032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:49:30

US3622032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:49:30

US3622032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:49:30

US3622032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'VISIT2'	System	14 Sep 2020 13:49:30

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '08:14'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '14 Sep 2020 08:14'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '87'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'bpm'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '20'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'breaths/min'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '109'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '71'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '10:04'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '14 Sep 2020 10:04'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '79'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'bpm'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '20'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'breaths/min'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '99'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '68'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	14 Sep 2020 19:59:42

US3622032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:49

US3622032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 19:59:49

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:00

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:00

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:00

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:00

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:00

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:00

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:00

US3622032

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered empty.	System	14 Sep 2020 20:02:00

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '09:33'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '14 Sep 2020 09:33'	System	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'ONCE'	System	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 13:50:59

US3622032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:17

US3622032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:17

US3622032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '08:23'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:17

US3622032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '14 Sep 2020 08:23'	System	14 Sep 2020 20:02:17

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered '08:29'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '14 Sep 2020 08:29'	System	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered empty.	System	14 Sep 2020 20:02:32

US3622032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 12:37:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 20:02:45

US3622032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '1'	System	14 Sep 2020 20:02:45

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:04', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dce28ca5-6806-4632-b0c0-5de7c5d302c7' User entered 'Yes (Y)'	System	14 Sep 2020 14:07:21
	System	14 Sep 2020 14:07:21

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:11', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dce28ca5-6806-4632-b0c0-5de7c5d302c7' User entered '98.8'	System	14 Sep 2020 14:07:21
	System	14 Sep 2020 14:07:21

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:14', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dce28ca5-6806-4632-b0c0-5de7c5d302c7'	System	14 Sep 2020 14:07:21
User entered 'No (N)'	System	14 Sep 2020 14:07:21

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:17', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'dce28ca5-6806-4632-b0c0-5de7c5d302c7' User entered '14 Sep 2020 10:07'	System	14 Sep 2020 14:07:21
	System	14 Sep 2020 14:07:21

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 09:53'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f3b2a0f6-0d01-409b-a58b-84aead55b692'	System	15 Sep 2020 02:09:12
User entered 'Yes (Y)'	System	15 Sep 2020 02:09:12

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:03', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f3b2a0f6-0d01-409b-a58b-84aead55b692' User entered '98.2'	System	15 Sep 2020 02:09:12
	System	15 Sep 2020 02:09:12

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:06', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f3b2a0f6-0d01-409b-a58b-84aead55b692'	System	15 Sep 2020 02:09:12
User entered 'No (N)'	System	15 Sep 2020 02:09:12

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:08', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f3b2a0f6-0d01-409b-a58b-84aead55b692'	System	15 Sep 2020 02:09:12
User entered '14 Sep 2020 22:09'	System	15 Sep 2020 02:09:12

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 13:18'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 2'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:35:52', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0c411011-8fab-40b3-924f-8c8bc15a3994' User entered 'Yes (Y)'	System	16 Sep 2020 01:36:04
	System	16 Sep 2020 01:36:04

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:35:55', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0c411011-8fab-40b3-924f-8c8bc15a3994' User entered '99.2'	System	16 Sep 2020 01:36:04
	System	16 Sep 2020 01:36:04

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:35:58', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0c411011-8fab-40b3-924f-8c8bc15a3994'	System	16 Sep 2020 01:36:04
User entered 'No (N)'	System	16 Sep 2020 01:36:04

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0c411011-8fab-40b3-924f-8c8bc15a3994' User entered '15 Sep 2020 21:36'	System	16 Sep 2020 01:36:04
	System	16 Sep 2020 01:36:04

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 3'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:04', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'eaf30846-a01c-44c6-8140-c65b87801ffe' User entered 'Yes (Y)'	System	17 Sep 2020 10:01:24
	System	17 Sep 2020 10:01:24

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:13', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'eaf30846-a01c-44c6-8140-c65b87801ffe' User entered '98.3'	System	17 Sep 2020 10:01:24
	System	17 Sep 2020 10:01:24

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:16', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'eaf30846-a01c-44c6-8140-c65b87801ffe' User entered 'No (N)'	System	17 Sep 2020 10:01:24
	System	17 Sep 2020 10:01:24

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:20', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'eaf30846-a01c-44c6-8140-c65b87801ffe' User entered '17 Sep 2020 06:01'	System	17 Sep 2020 10:01:24
	System	17 Sep 2020 10:01:24

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 4'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:12', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf27d7bc-b6c2-4ba6-a899-bf7d58acfaba' User entered 'Yes (Y)'	System	18 Sep 2020 03:59:26
	System	18 Sep 2020 03:59:26

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:16', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf27d7bc-b6c2-4ba6-a899-bf7d58acfaba' User entered '98.3'	System	18 Sep 2020 03:59:26
	System	18 Sep 2020 03:59:26

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:18', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf27d7bc-b6c2-4ba6-a899-bf7d58acfaba' User entered 'No (N)'	System	18 Sep 2020 03:59:26
	System	18 Sep 2020 03:59:26

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:21', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf27d7bc-b6c2-4ba6-a899-bf7d58acfaba' User entered '17 Sep 2020 23:59'	System	18 Sep 2020 03:59:26
	System	18 Sep 2020 03:59:26

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 5'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:06', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4c424d37-8783-442c-a54c-36ce3d3073fd' User entered 'Yes (Y)'	System	19 Sep 2020 00:55:17
	System	19 Sep 2020 00:55:17

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:11', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4c424d37-8783-442c-a54c-36ce3d3073fd' User entered '98.4'	System	19 Sep 2020 00:55:17
	System	19 Sep 2020 00:55:17

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:13', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4c424d37-8783-442c-a54c-36ce3d3073fd' User entered 'No (N)'	System	19 Sep 2020 00:55:17
	System	19 Sep 2020 00:55:17

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:15', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4c424d37-8783-442c-a54c-36ce3d3073fd' User entered '18 Sep 2020 20:55'	System	19 Sep 2020 00:55:17
	System	19 Sep 2020 00:55:17

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 6'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:19:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4acb5226-d452-4797-be45-c33dbc0f2e8b' User entered 'Yes (Y)'	System	20 Sep 2020 01:19:51
	System	20 Sep 2020 01:19:51

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:19:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4acb5226-d452-4797-be45-c33dbc0f2e8b' User entered '97.2'	System	20 Sep 2020 01:19:51
	System	20 Sep 2020 01:19:51

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:19:46', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4acb5226-d452-4797-be45-c33dbc0f2e8b' User entered 'No (N)'	System	20 Sep 2020 01:19:51
	System	20 Sep 2020 01:19:51

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:19:48', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4acb5226-d452-4797-be45-c33dbc0f2e8b' User entered '19 Sep 2020 21:19'	System	20 Sep 2020 01:19:51
	System	20 Sep 2020 01:19:51

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 7'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:15', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '33a4e5a5-c8b0-4144-871b-f8eccc5fdc3f' User entered 'Yes (Y)'	System	21 Sep 2020 01:15:26
	System	21 Sep 2020 01:15:26

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:19', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '33a4e5a5-c8b0-4144-871b-f8eccc5fdc3f' User entered '97.4'	System	21 Sep 2020 01:15:26
	System	21 Sep 2020 01:15:26

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:21', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '33a4e5a5-c8b0-4144-871b-f8eccc5fdc3f' User entered 'No (N)'	System	21 Sep 2020 01:15:26
	System	21 Sep 2020 01:15:26

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:23', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '33a4e5a5-c8b0-4144-871b-f8eccc5fdc3f' User entered '20 Sep 2020 21:15'	System	21 Sep 2020 01:15:26
	System	21 Sep 2020 01:15:26

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:25', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b2c11ba6-227c-44be-8afa-5c51a506ea7f' User entered 'None (1)'	System	14 Sep 2020 14:07:51
	System	14 Sep 2020 14:07:51

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b2c11ba6-227c-44be-8afa-5c51a506ea7f' User entered 'No (N)'	System	14 Sep 2020 14:07:51
	System	14 Sep 2020 14:07:51

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b2c11ba6-227c-44be-8afa-5c51a506ea7f' User entered 'No (N)'	System	14 Sep 2020 14:07:51
	System	14 Sep 2020 14:07:51

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b2c11ba6-227c-44be-8afa-5c51a506ea7f' User entered 'None (1)'	System	14 Sep 2020 14:07:51
	System	14 Sep 2020 14:07:51

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:49', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b2c11ba6-227c-44be-8afa-5c51a506ea7f' User entered '14 Sep 2020 10:07'	System	14 Sep 2020 14:07:51
	System	14 Sep 2020 14:07:51

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 09:53'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:12', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37027ab0-8f85-4230-853d-23496e13e33d' User entered 'None (1)'	System	15 Sep 2020 02:09:24
	System	15 Sep 2020 02:09:24

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:14', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37027ab0-8f85-4230-853d-23496e13e33d' User entered 'No (N)'	System	15 Sep 2020 02:09:24
	System	15 Sep 2020 02:09:24

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:17', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37027ab0-8f85-4230-853d-23496e13e33d' User entered 'No (N)'	System	15 Sep 2020 02:09:24
	System	15 Sep 2020 02:09:24

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:20', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37027ab0-8f85-4230-853d-23496e13e33d' User entered 'None (1)'	System	15 Sep 2020 02:09:24
	System	15 Sep 2020 02:09:24

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:22', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37027ab0-8f85-4230-853d-23496e13e33d' User entered '14 Sep 2020 22:09'	System	15 Sep 2020 02:09:24
	System	15 Sep 2020 02:09:24

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 13:18'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 2'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:05', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'a28da347-4db7-4b3d-aba6-46c7a58053de' User entered 'None (1)'	System	16 Sep 2020 01:36:16
	System	16 Sep 2020 01:36:16

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:08', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'a28da347-4db7-4b3d-aba6-46c7a58053de' User entered 'No (N)'	System	16 Sep 2020 01:36:16
	System	16 Sep 2020 01:36:16

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:09', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'a28da347-4db7-4b3d-aba6-46c7a58053de' User entered 'No (N)'	System	16 Sep 2020 01:36:16
	System	16 Sep 2020 01:36:16

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:11', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'a28da347-4db7-4b3d-aba6-46c7a58053de' User entered 'None (1)'	System	16 Sep 2020 01:36:16
	System	16 Sep 2020 01:36:16

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:13', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'a28da347-4db7-4b3d-aba6-46c7a58053de' User entered '15 Sep 2020 21:36'	System	16 Sep 2020 01:36:16
	System	16 Sep 2020 01:36:16

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 3'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:24', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf19e07f-c583-4c51-8559-212eebceb2cf' User entered 'None (1)'	System	17 Sep 2020 10:01:37
	System	17 Sep 2020 10:01:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf19e07f-c583-4c51-8559-212eebceb2cf' User entered 'No (N)'	System	17 Sep 2020 10:01:37
	System	17 Sep 2020 10:01:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:30', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf19e07f-c583-4c51-8559-212eebceb2cf' User entered 'No (N)'	System	17 Sep 2020 10:01:37
	System	17 Sep 2020 10:01:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:32', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf19e07f-c583-4c51-8559-212eebceb2cf' User entered 'None (1)'	System	17 Sep 2020 10:01:37
	System	17 Sep 2020 10:01:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bf19e07f-c583-4c51-8559-212eebceb2cf' User entered '17 Sep 2020 06:01'	System	17 Sep 2020 10:01:37
	System	17 Sep 2020 10:01:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 4'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:25', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '726958b4-c32c-456b-b174-be47523bcd22'	System	18 Sep 2020 03:59:56
User entered 'None (1)'	System	18 Sep 2020 03:59:56

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:27', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '726958b4-c32c-456b-b174-be47523bcd22'	System	18 Sep 2020 03:59:56
User entered 'No (N)'	System	18 Sep 2020 03:59:56

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '726958b4-c32c-456b-b174-be47523bcd22'	System	18 Sep 2020 03:59:56
User entered 'No (N)'	System	18 Sep 2020 03:59:56

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:32', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '726958b4-c32c-456b-b174-be47523bcd22'	System	18 Sep 2020 03:59:56
User entered 'None (1)'	System	18 Sep 2020 03:59:56

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:34', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '726958b4-c32c-456b-b174-be47523bcd22'	System	18 Sep 2020 03:59:56
User entered '17 Sep 2020 23:59'	System	18 Sep 2020 03:59:56

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 5'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:18', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '115223b5-d232-4371-9586-405383760c66'	System	19 Sep 2020 00:55:31
User entered 'None (1)'	System	19 Sep 2020 00:55:31

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:21', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '115223b5-d232-4371-9586-405383760c66'	System	19 Sep 2020 00:55:31
User entered 'No (N)'	System	19 Sep 2020 00:55:31

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:23', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '115223b5-d232-4371-9586-405383760c66'	System	19 Sep 2020 00:55:31
User entered 'No (N)'	System	19 Sep 2020 00:55:31

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:25', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '115223b5-d232-4371-9586-405383760c66'	System	19 Sep 2020 00:55:31
User entered 'None (1)'	System	19 Sep 2020 00:55:31

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '115223b5-d232-4371-9586-405383760c66' User entered '18 Sep 2020 20:55'	System	19 Sep 2020 00:55:31
	System	19 Sep 2020 00:55:31

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 6'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:09', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37ede4bb-4d41-481d-a99e-9fd6cebe6a80'	System	20 Sep 2020 01:22:20
User entered 'None (1)'	System	20 Sep 2020 01:22:20

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:12', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37ede4bb-4d41-481d-a99e-9fd6cebe6a80' User entered 'No (N)'	System	20 Sep 2020 01:22:20
	System	20 Sep 2020 01:22:20

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:14', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37ede4bb-4d41-481d-a99e-9fd6cebe6a80' User entered 'No (N)'	System	20 Sep 2020 01:22:20
	System	20 Sep 2020 01:22:20

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:15', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37ede4bb-4d41-481d-a99e-9fd6cebe6a80'	System	20 Sep 2020 01:22:20
User entered 'None (1)'	System	20 Sep 2020 01:22:20

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:18', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '37ede4bb-4d41-481d-a99e-9fd6cebe6a80' User entered '19 Sep 2020 21:22'	System	20 Sep 2020 01:22:20
	System	20 Sep 2020 01:22:20

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 7'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '63124291-2f00-405b-b15e-2894780f1aa3'	System	21 Sep 2020 01:15:37
User entered 'None (1)'	System	21 Sep 2020 01:15:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '63124291-2f00-405b-b15e-2894780f1aa3' User entered 'No (N)'	System	21 Sep 2020 01:15:37
	System	21 Sep 2020 01:15:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '63124291-2f00-405b-b15e-2894780f1aa3'	System	21 Sep 2020 01:15:37
User entered 'No (N)'	System	21 Sep 2020 01:15:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:32', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '63124291-2f00-405b-b15e-2894780f1aa3' User entered 'None (1)'	System	21 Sep 2020 01:15:37
	System	21 Sep 2020 01:15:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '63124291-2f00-405b-b15e-2894780f1aa3' User entered '20 Sep 2020 21:15'	System	21 Sep 2020 01:15:37
	System	21 Sep 2020 01:15:37

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:52', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ca96e57d-4938-4582-9216-71b4762a5ad3' User entered 'None (0)'	System	14 Sep 2020 14:08:09
	System	14 Sep 2020 14:08:09

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:54', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ca96e57d-4938-4582-9216-71b4762a5ad3' User entered 'None (0)'	System	14 Sep 2020 14:08:09
	System	14 Sep 2020 14:08:09

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:57', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ca96e57d-4938-4582-9216-71b4762a5ad3' User entered 'None (0)'	System	14 Sep 2020 14:08:09
	System	14 Sep 2020 14:08:09

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:07:58', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ca96e57d-4938-4582-9216-71b4762a5ad3' User entered 'None (0)'	System	14 Sep 2020 14:08:09
	System	14 Sep 2020 14:08:09

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:08:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ca96e57d-4938-4582-9216-71b4762a5ad3' User entered 'None (0)'	System	14 Sep 2020 14:08:09
	System	14 Sep 2020 14:08:09

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:08:02', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ca96e57d-4938-4582-9216-71b4762a5ad3' User entered 'None (0)'	System	14 Sep 2020 14:08:09
	System	14 Sep 2020 14:08:09

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:08:04', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ca96e57d-4938-4582-9216-71b4762a5ad3'	System	14 Sep 2020 14:08:09
User entered 'No (N)'	System	14 Sep 2020 14:08:09

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T10:08:06', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ca96e57d-4938-4582-9216-71b4762a5ad3' User entered '14 Sep 2020 10:08'	System	14 Sep 2020 14:08:09
	System	14 Sep 2020 14:08:09

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 09:53'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '96b56ebc-900d-4ad3-82ab-806672c3ebde' User entered 'None (0)'	System	15 Sep 2020 02:09:44
	System	15 Sep 2020 02:09:44

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:28', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '96b56ebc-900d-4ad3-82ab-806672c3ebde' User entered 'None (0)'	System	15 Sep 2020 02:09:44
	System	15 Sep 2020 02:09:44

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '96b56ebc-900d-4ad3-82ab-806672c3ebde' User entered 'None (0)'	System	15 Sep 2020 02:09:44
	System	15 Sep 2020 02:09:44

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '96b56ebc-900d-4ad3-82ab-806672c3ebde' User entered 'None (0)'	System	15 Sep 2020 02:09:44
	System	15 Sep 2020 02:09:44

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:33', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '96b56ebc-900d-4ad3-82ab-806672c3ebde' User entered 'None (0)'	System	15 Sep 2020 02:09:44
	System	15 Sep 2020 02:09:44

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:34', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '96b56ebc-900d-4ad3-82ab-806672c3ebde' User entered 'None (0)'	System	15 Sep 2020 02:09:44
	System	15 Sep 2020 02:09:44

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:37', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '96b56ebc-900d-4ad3-82ab-806672c3ebde' User entered 'No (N)'	System	15 Sep 2020 02:09:44
	System	15 Sep 2020 02:09:44

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-14T22:09:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '96b56ebc-900d-4ad3-82ab-806672c3ebde' User entered '14 Sep 2020 22:09'	System	15 Sep 2020 02:09:44
	System	15 Sep 2020 02:09:44

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '14 Sep 2020 13:18'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 2'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:16', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b949cb41-7b52-4148-9849-526ec13c5813' User entered 'None (0)'	System	16 Sep 2020 01:36:37
	System	16 Sep 2020 01:36:37

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:18', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b949cb41-7b52-4148-9849-526ec13c5813' User entered 'None (0)'	System	16 Sep 2020 01:36:37
	System	16 Sep 2020 01:36:37

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:19', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b949cb41-7b52-4148-9849-526ec13c5813' User entered 'None (0)'	System	16 Sep 2020 01:36:37
	System	16 Sep 2020 01:36:37

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:21', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b949cb41-7b52-4148-9849-526ec13c5813' User entered 'None (0)'	System	16 Sep 2020 01:36:37
	System	16 Sep 2020 01:36:37

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:22', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b949cb41-7b52-4148-9849-526ec13c5813' User entered 'None (0)'	System	16 Sep 2020 01:36:37
	System	16 Sep 2020 01:36:37

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:24', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b949cb41-7b52-4148-9849-526ec13c5813' User entered 'None (0)'	System	16 Sep 2020 01:36:37
	System	16 Sep 2020 01:36:37

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b949cb41-7b52-4148-9849-526ec13c5813'	System	16 Sep 2020 01:36:37
User entered 'No (N)'	System	16 Sep 2020 01:36:37

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-15T21:36:33', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'b949cb41-7b52-4148-9849-526ec13c5813'	System	16 Sep 2020 01:36:37
User entered '15 Sep 2020 21:36'	System	16 Sep 2020 01:36:37

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 3'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:39', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ac1f15ff-279b-4d05-b50d-8c1e92591046'	System	17 Sep 2020 10:01:58
User entered 'None (0)'	System	17 Sep 2020 10:01:58

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ac1f15ff-279b-4d05-b50d-8c1e92591046'	System	17 Sep 2020 10:01:58
User entered 'None (0)'	System	17 Sep 2020 10:01:58

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:42', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ac1f15ff-279b-4d05-b50d-8c1e92591046' User entered 'None (0)'	System	17 Sep 2020 10:01:58
	System	17 Sep 2020 10:01:58

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ac1f15ff-279b-4d05-b50d-8c1e92591046' User entered 'None (0)'	System	17 Sep 2020 10:01:58
	System	17 Sep 2020 10:01:58

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:46', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ac1f15ff-279b-4d05-b50d-8c1e92591046' User entered 'None (0)'	System	17 Sep 2020 10:01:58
	System	17 Sep 2020 10:01:58

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:48', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ac1f15ff-279b-4d05-b50d-8c1e92591046'	System	17 Sep 2020 10:01:58
User entered 'None (0)'	System	17 Sep 2020 10:01:58

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:53', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ac1f15ff-279b-4d05-b50d-8c1e92591046'	System	17 Sep 2020 10:01:58
User entered 'No (N)'	System	17 Sep 2020 10:01:58

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T06:01:57', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ac1f15ff-279b-4d05-b50d-8c1e92591046' User entered '17 Sep 2020 06:01'	System	17 Sep 2020 10:01:58
	System	17 Sep 2020 10:01:58

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 4'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:38', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0bae3b4a-88e5-4424-be1f-eca9bcfe701b' User entered 'None (0)'	System	19 Sep 2020 00:55:15
	System	19 Sep 2020 00:55:15

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:39', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0bae3b4a-88e5-4424-be1f-eca9bcfe701b' User entered 'None (0)'	System	19 Sep 2020 00:55:15
	System	19 Sep 2020 00:55:15

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0bae3b4a-88e5-4424-be1f-eca9bcfe701b' User entered 'None (0)'	System	19 Sep 2020 00:55:15
	System	19 Sep 2020 00:55:15

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0bae3b4a-88e5-4424-be1f-eca9bcfe701b' User entered 'None (0)'	System	19 Sep 2020 00:55:15
	System	19 Sep 2020 00:55:15

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0bae3b4a-88e5-4424-be1f-eca9bcfe701b' User entered 'None (0)'	System	19 Sep 2020 00:55:15
	System	19 Sep 2020 00:55:15

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:46', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0bae3b4a-88e5-4424-be1f-eca9bcfe701b' User entered 'None (0)'	System	19 Sep 2020 00:55:15
	System	19 Sep 2020 00:55:15

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:49', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0bae3b4a-88e5-4424-be1f-eca9bcfe701b' User entered 'No (N)'	System	19 Sep 2020 00:55:15
	System	19 Sep 2020 00:55:15

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-17T23:59:51', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '0bae3b4a-88e5-4424-be1f-eca9bcfe701b' User entered '17 Sep 2020 23:59'	System	19 Sep 2020 00:55:15
	System	19 Sep 2020 00:55:15

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 5'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:32', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'cb0c91fd-d67c-44d0-b066-17fdd96c7b1d' User entered 'None (0)'	System	19 Sep 2020 00:55:47
	System	19 Sep 2020 00:55:47

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:34', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'cb0c91fd-d67c-44d0-b066-17fdd96c7b1d' User entered 'None (0)'	System	19 Sep 2020 00:55:47
	System	19 Sep 2020 00:55:47

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:35', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'cb0c91fd-d67c-44d0-b066-17fdd96c7b1d' User entered 'None (0)'	System	19 Sep 2020 00:55:47
	System	19 Sep 2020 00:55:47

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:37', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'cb0c91fd-d67c-44d0-b066-17fdd96c7b1d' User entered 'None (0)'	System	19 Sep 2020 00:55:47
	System	19 Sep 2020 00:55:47

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:39', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'cb0c91fd-d67c-44d0-b066-17fdd96c7b1d' User entered 'None (0)'	System	19 Sep 2020 00:55:47
	System	19 Sep 2020 00:55:47

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'cb0c91fd-d67c-44d0-b066-17fdd96c7b1d' User entered 'None (0)'	System	19 Sep 2020 00:55:47
	System	19 Sep 2020 00:55:47

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:42', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'cb0c91fd-d67c-44d0-b066-17fdd96c7b1d' User entered 'No (N)'	System	19 Sep 2020 00:55:47
	System	19 Sep 2020 00:55:47

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-18T20:55:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'cb0c91fd-d67c-44d0-b066-17fdd96c7b1d' User entered '18 Sep 2020 20:55'	System	19 Sep 2020 00:55:47
	System	19 Sep 2020 00:55:47

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 6'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:21', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'afcded0b-2f54-43b2-a108-e2713e33e77e' User entered 'None (0)'	System	20 Sep 2020 01:22:35
	System	20 Sep 2020 01:22:35

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:22', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'afcded0b-2f54-43b2-a108-e2713e33e77e' User entered 'None (0)'	System	20 Sep 2020 01:22:35
	System	20 Sep 2020 01:22:35

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:25', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'afcded0b-2f54-43b2-a108-e2713e33e77e' User entered 'None (0)'	System	20 Sep 2020 01:22:35
	System	20 Sep 2020 01:22:35

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'afcded0b-2f54-43b2-a108-e2713e33e77e' User entered 'None (0)'	System	20 Sep 2020 01:22:35
	System	20 Sep 2020 01:22:35

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:28', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'afcded0b-2f54-43b2-a108-e2713e33e77e' User entered 'None (0)'	System	20 Sep 2020 01:22:35
	System	20 Sep 2020 01:22:35

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'afcded0b-2f54-43b2-a108-e2713e33e77e' User entered 'None (0)'	System	20 Sep 2020 01:22:35
	System	20 Sep 2020 01:22:35

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:31', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'afcded0b-2f54-43b2-a108-e2713e33e77e' User entered 'No (N)'	System	20 Sep 2020 01:22:35
	System	20 Sep 2020 01:22:35

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-19T21:22:33', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'afcded0b-2f54-43b2-a108-e2713e33e77e' User entered '19 Sep 2020 21:22'	System	20 Sep 2020 01:22:35
	System	20 Sep 2020 01:22:35

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	14 Sep 2020 13:50:59
User entered 'Day 7'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:38', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '450402ef-95af-41d0-9031-f7cf8dad7cdc' User entered 'None (0)'	System	21 Sep 2020 01:15:56
	System	21 Sep 2020 01:15:56

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '450402ef-95af-41d0-9031-f7cf8dad7cdc' User entered 'None (0)'	System	21 Sep 2020 01:15:56
	System	21 Sep 2020 01:15:56

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '450402ef-95af-41d0-9031-f7cf8dad7cdc' User entered 'None (0)'	System	21 Sep 2020 01:15:56
	System	21 Sep 2020 01:15:56

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '450402ef-95af-41d0-9031-f7cf8dad7cdc' User entered 'None (0)'	System	21 Sep 2020 01:15:56
	System	21 Sep 2020 01:15:56

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:44', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '450402ef-95af-41d0-9031-f7cf8dad7cdc' User entered 'None (0)'	System	21 Sep 2020 01:15:56
	System	21 Sep 2020 01:15:56

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '450402ef-95af-41d0-9031-f7cf8dad7cdc' User entered 'None (0)'	System	21 Sep 2020 01:15:56
	System	21 Sep 2020 01:15:56

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:50', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '450402ef-95af-41d0-9031-f7cf8dad7cdc' User entered 'No (N)'	System	21 Sep 2020 01:15:56
	System	21 Sep 2020 01:15:56

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-09-20T21:15:52', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '450402ef-95af-41d0-9031-f7cf8dad7cdc' User entered '20 Sep 2020 21:15'	System	21 Sep 2020 01:15:56
	System	21 Sep 2020 01:15:56

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 13:50:59

US3622032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 23:02:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 13:50:59

US3622032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered 'Yes (Y)'	Junlin Long	29 Sep 2020 13:23:34

US3622032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered '21 Sep 2020'	Junlin Long (b) (4)	29 Sep 2020 13:23:34

US3622032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	29 Sep 2020 13:23:34

US3622032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered empty.	Junlin Long (b) (4)	29 Sep 2020 13:23:34

US3622032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered 'Yes (Y)'	Junlin Long	29 Sep 2020 13:23:40

US3622032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'I'	System	29 Sep 2020 13:23:40

US3622032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered 'Yes (Y)'	Junlin Long	05 Oct 2020 17:32:20

US3622032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered '28 Sep 2020'	Junlin Long	05 Oct 2020 17:32:20

US3622032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered 'Contact Made (CONTACT MADE)'	Junlin Long	05 Oct 2020 17:32:20

US3622032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered empty.	Junlin Long (b) (4)	05 Oct 2020 17:32:20

US3622032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 11:50:51
User entered 'Yes (Y)'	Junlin Long	05 Oct 2020 17:32:10

US3622032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'I'	System	05 Oct 2020 17:32:10

US3622032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:47:26
User entered 'Yes (Y)'	Junlin Long	09 Oct 2020 13:43:23

US3622032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:47:26
User entered '8 Oct 2020'	Junlin Long	09 Oct 2020 13:43:23

US3622032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:47:26
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	09 Oct 2020 13:43:23

US3622032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:47:26
User entered empty.	Junlin Long (b) (4)	09 Oct 2020 13:43:23

US3622032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	10 Oct 2020 17:47:16
User entered 'Yes (Y)'	Junlin Long	09 Oct 2020 13:43:28

US3622032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'I'	System	09 Oct 2020 13:43:28

US3622032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered 'Yes (Y)'	Junlin Long	12 Oct 2020 12:40:48

US3622032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '12 Oct 2020'	Junlin Long	12 Oct 2020 12:40:48

US3622032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered 'Clinic (Clinic)'	Junlin Long	12 Oct 2020 12:40:48

US3622032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'VISIT3'	System	12 Oct 2020 12:40:48

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered 'Yes (Y)'	Junlin Long	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '12 Oct 2020'	Junlin Long (b) (4)	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '08:30'	Junlin Long	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '12 Oct 2020 08:30'	System	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '98.4' F	Junlin Long (b) (4)	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered 'Oral (Oral)'	Junlin Long	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered empty.	Junlin Long	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '78'	Junlin Long	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'bpm'	System	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '16'	Junlin Long	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'breaths/min'	System	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '104'	Junlin Long	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '70'	Junlin Long	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'mmHg'	System	12 Oct 2020 12:41:53

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19

US3622032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19

US3622032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered 'No (N)'	Junlin Long	12 Oct 2020 12:41:59

US3622032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered empty.	Junlin Long	12 Oct 2020 12:41:59

US3622032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered 'Yes (Y)'	Junlin Long	12 Oct 2020 12:42:11

US3622032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '12 Oct 2020'	Junlin Long (b) (4)	12 Oct 2020 12:42:11

US3622032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered '8:40'	Junlin Long (b) (4)	12 Oct 2020 12:42:11

US3622032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '12 Oct 2020 8:40'	System	12 Oct 2020 12:42:11

US3622032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 19:43:04
User entered 'Yes (Y)'	Junlin Long	12 Oct 2020 12:42:15

US3622032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered '1'	System	12 Oct 2020 12:42:15

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 64'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-17T07:56:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3e997938-bf0f-4b0e-9a10-43e8a738da5f' User entered 'No (N)'	System	17 Oct 2020 11:56:58
	System	17 Oct 2020 11:56:58

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-17T07:56:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3e997938-bf0f-4b0e-9a10-43e8a738da5f'	System	17 Oct 2020 11:56:58
User entered 'No (N)'	System	17 Oct 2020 11:56:58

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-17T07:56:55', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3e997938-bf0f-4b0e-9a10-43e8a738da5f' User entered '17 Oct 2020 07:56:55'	System	17 Oct 2020 11:56:58
	System	17 Oct 2020 11:56:58

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 71'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-24T20:13:51', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '89ad498e-ae1b-4a8f-97ba-3924c4589204'	System	25 Oct 2020 00:14:02
User entered 'No (N)'	System	25 Oct 2020 00:14:02

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-24T20:13:57', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '89ad498e-ae1b-4a8f-97ba-3924c4589204'	System	25 Oct 2020 00:14:02
User entered 'No (N)'	System	25 Oct 2020 00:14:02

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-24T20:14:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '89ad498e-ae1b-4a8f-97ba-3924c4589204' User entered '24 Oct 2020 20:14:00'	System	25 Oct 2020 00:14:02
	System	25 Oct 2020 00:14:02

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 78'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-31T07:34:57', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'fff1e281-8c2d-4781-a2cd-42544bb5553e'	System	31 Oct 2020 11:35:10
User entered 'No (N)'	System	31 Oct 2020 11:35:10

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-31T07:35:04', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'fff1e281-8c2d-4781-a2cd-42544bb5553e'	System	31 Oct 2020 11:35:10
User entered 'No (N)'	System	31 Oct 2020 11:35:10

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-10-31T07:35:06', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'fff1e281-8c2d-4781-a2cd-42544bb5553e' User entered '31 Oct 2020 07:35:06'	System	31 Oct 2020 11:35:10
	System	31 Oct 2020 11:35:10

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered 'Day 92'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-11-14T23:29:52', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ce026f2b-d766-4e1d-bdf0-732555ad7e97'	System	15 Nov 2020 04:30:02
User entered 'No (N)'	System	15 Nov 2020 04:30:02

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-11-14T23:29:55', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ce026f2b-d766-4e1d-bdf0-732555ad7e97'	System	15 Nov 2020 04:30:02
User entered 'No (N)'	System	15 Nov 2020 04:30:02

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-11-14T23:29:58', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'ce026f2b-d766-4e1d-bdf0-732555ad7e97'	System	15 Nov 2020 04:30:02
User entered '14 Nov 2020 23:29:58'	System	15 Nov 2020 04:30:02

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 12:53:54

US3622032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:11:35
Data entry locked.	System	17 Aug 2020 12:53:54
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 12:53:54

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-11-25T02:28:28', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f65213de-cb89-4616-a013-16a9b30a4aad' User entered 'No (N)'	System	25 Nov 2020 07:28:41

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-11-25T02:28:34', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f65213de-cb89-4616-a013-16a9b30a4aad' User entered 'No (N)'	System	25 Nov 2020 07:28:41

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-11-25T02:28:37', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f65213de-cb89-4616-a013-16a9b30a4aad' User entered '25 Nov 2020 02:28:37'	System	25 Nov 2020 07:28:41
	System	25 Nov 2020 07:28:41

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-02T06:39:42', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f72a7f23-2d85-4f8a-abd8-5341997e2298'	System	02 Dec 2020 11:39:58
User entered 'No (N)'	System	02 Dec 2020 11:39:58

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-02T06:39:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f72a7f23-2d85-4f8a-abd8-5341997e2298'	System	02 Dec 2020 11:39:58
User entered 'No (N)'	System	02 Dec 2020 11:39:58

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-02T06:39:52', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f72a7f23-2d85-4f8a-abd8-5341997e2298' User entered '02 Dec 2020 06:39:52'	System	02 Dec 2020 11:39:58
	System	02 Dec 2020 11:39:58

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-09T06:22:16', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c364ca70-724f-424b-af17-e9b2a61abff5'	System	09 Dec 2020 11:22:29
User entered 'No (N)'	System	09 Dec 2020 11:22:29

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-09T06:22:22', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c364ca70-724f-424b-af17-e9b2a61abff5'	System	09 Dec 2020 11:22:29
User entered 'No (N)'	System	09 Dec 2020 11:22:29

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-09T06:22:26', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c364ca70-724f-424b-af17-e9b2a61abff5' User entered '09 Dec 2020 06:22:26'	System	09 Dec 2020 11:22:29
	System	09 Dec 2020 11:22:29

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-16T15:25:42', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '733f4e5d-2678-4663-98e4-68c3c4c7215b' User entered 'No (N)'	System	16 Dec 2020 20:25:49
	System	16 Dec 2020 20:25:49

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-16T15:25:45', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '733f4e5d-2678-4663-98e4-68c3c4c7215b' User entered 'No (N)'	System	16 Dec 2020 20:25:49
	System	16 Dec 2020 20:25:49

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-16T15:25:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '733f4e5d-2678-4663-98e4-68c3c4c7215b' User entered '16 Dec 2020 15:25:47'	System	16 Dec 2020 20:25:49
	System	16 Dec 2020 20:25:49

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-23T00:01:14', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5ce1e5a7-9656-462f-8434-facaf30eefa8' User entered 'No (N)'	System	23 Dec 2020 05:01:26
	System	23 Dec 2020 05:01:26

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-23T00:01:17', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5ce1e5a7-9656-462f-8434-facaf30eefa8' User entered 'No (N)'	System	23 Dec 2020 05:01:26
	System	23 Dec 2020 05:01:26

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-23T00:01:19', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5ce1e5a7-9656-462f-8434-facaf30eefa8' User entered '23 Dec 2020 00:01:19'	System	23 Dec 2020 05:01:26
	System	23 Dec 2020 05:01:26

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-30T06:45:44', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5592bd4c-5760-460c-a32b-fe03d6270bc9' User entered 'No (N)'	System	30 Dec 2020 11:45:54
	System	30 Dec 2020 11:45:54

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-30T06:45:47', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5592bd4c-5760-460c-a32b-fe03d6270bc9' User entered 'No (N)'	System	30 Dec 2020 11:45:54
	System	30 Dec 2020 11:45:54

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2020-12-30T06:45:50', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5592bd4c-5760-460c-a32b-fe03d6270bc9' User entered '30 Dec 2020 06:45:50'	System	30 Dec 2020 11:45:54
	System	30 Dec 2020 11:45:54

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-07T12:21:10', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '2398ac54-67e5-4365-935a-41df13cf7514' User entered 'No (N)'	System	07 Jan 2021 17:21:18
	System	07 Jan 2021 17:21:18

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-07T12:21:13', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '2398ac54-67e5-4365-935a-41df13cf7514'	System	07 Jan 2021 17:21:18
User entered 'No (N)'	System	07 Jan 2021 17:21:18

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-07T12:21:16', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '2398ac54-67e5-4365-935a-41df13cf7514' User entered '07 Jan 2021 12:21:16'	System	07 Jan 2021 17:21:18
	System	07 Jan 2021 17:21:18

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-13T19:43:34', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '13416775-637a-458c-999f-73aaceb48eb0'	System	14 Jan 2021 00:43:45
User entered 'No (N)'	System	14 Jan 2021 00:43:45

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-13T19:43:38', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '13416775-637a-458c-999f-73aaceb48eb0'	System	14 Jan 2021 00:43:45
User entered 'No (N)'	System	14 Jan 2021 00:43:45

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-13T19:43:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '13416775-637a-458c-999f-73aaceb48eb0' User entered '13 Jan 2021 19:43:41'	System	14 Jan 2021 00:43:45
	System	14 Jan 2021 00:43:45

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-21T02:43:19', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'befe2f30-81b6-4dc0-a8c5-50e5bd27b9ec'	System	21 Jan 2021 07:43:34
User entered 'No (N)'	System	21 Jan 2021 07:43:34

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-21T02:43:25', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'befe2f30-81b6-4dc0-a8c5-50e5bd27b9ec'	System	21 Jan 2021 07:43:34
User entered 'No (N)'	System	21 Jan 2021 07:43:34

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-21T02:43:29', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'befe2f30-81b6-4dc0-a8c5-50e5bd27b9ec'	System	21 Jan 2021 07:43:34
User entered '21 Jan 2021 02:43:29'	System	21 Jan 2021 07:43:34

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-28T20:28:36', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '7b63eb7e-8de5-4a45-a654-8f274e0424d7' User entered 'No (N)'	System	29 Jan 2021 01:28:46

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-28T20:28:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '7b63eb7e-8de5-4a45-a654-8f274e0424d7' User entered 'No (N)'	System	29 Jan 2021 01:28:46

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-01-28T20:28:43', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '7b63eb7e-8de5-4a45-a654-8f274e0424d7' User entered '28 Jan 2021 20:28:43'	System	29 Jan 2021 01:28:46
	System	29 Jan 2021 01:28:46

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-06T14:09:55', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'e73bd735-9b8f-4b0c-be5c-c0410ff40254'	System	06 Feb 2021 19:33:27
User entered 'No (N)'	System	06 Feb 2021 19:33:27

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-06T14:09:57', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'e73bd735-9b8f-4b0c-be5c-c0410ff40254'	System	06 Feb 2021 19:33:27
User entered 'No (N)'	System	06 Feb 2021 19:33:27

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-06T14:10:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'e73bd735-9b8f-4b0c-be5c-c0410ff40254' User entered '06 Feb 2021 14:10:00'	System	06 Feb 2021 19:33:27
	System	06 Feb 2021 19:33:27

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-10T22:19:27', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c1ffa6d6-22e0-437c-9db1-24d51937865e' User entered 'No (N)'	System	11 Feb 2021 03:19:34
	System	11 Feb 2021 03:19:34

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-10T22:19:30', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c1ffa6d6-22e0-437c-9db1-24d51937865e'	System	11 Feb 2021 03:19:34
User entered 'No (N)'	System	11 Feb 2021 03:19:34

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-10T22:19:32', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'c1ffa6d6-22e0-437c-9db1-24d51937865e' User entered '10 Feb 2021 22:19:32'	System	11 Feb 2021 03:19:34
	System	11 Feb 2021 03:19:34

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-17T19:27:52', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bd701a34-60e6-4b1a-9a4a-7d95a78c4f98'	System	18 Feb 2021 00:27:58
User entered 'No (N)'	System	18 Feb 2021 00:27:58

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-17T19:27:53', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bd701a34-60e6-4b1a-9a4a-7d95a78c4f98'	System	18 Feb 2021 00:27:58
User entered 'No (N)'	System	18 Feb 2021 00:27:58

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-17T19:27:56', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bd701a34-60e6-4b1a-9a4a-7d95a78c4f98'	System	18 Feb 2021 00:27:58
User entered '17 Feb 2021 19:27:56'	System	18 Feb 2021 00:27:58

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-25T23:15:48', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '961d6c09-1be5-448a-b5c9-5f511a24311e' User entered 'No (N)'	System	26 Feb 2021 04:16:08
	System	26 Feb 2021 04:16:08

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-25T23:15:50', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '961d6c09-1be5-448a-b5c9-5f511a24311e' User entered 'No (N)'	System	26 Feb 2021 04:16:08
	System	26 Feb 2021 04:16:08

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-02-25T23:16:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '961d6c09-1be5-448a-b5c9-5f511a24311e' User entered '25 Feb 2021 23:16:00'	System	26 Feb 2021 04:16:08
	System	26 Feb 2021 04:16:08

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-04T21:08:40', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bdbcf7d8-ac69-462a-aa69-f91b12c2c47e' User entered 'No (N)'	System	10 Mar 2021 02:52:11
	System	10 Mar 2021 02:52:11

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-04T21:08:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bdbcf7d8-ac69-462a-aa69-f91b12c2c47e' User entered 'No (N)'	System	10 Mar 2021 02:52:11

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-04T21:08:44', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'bdbcf7d8-ac69-462a-aa69-f91b12c2c47e' User entered '04 Mar 2021 21:08:44'	System	10 Mar 2021 02:52:11
	System	10 Mar 2021 02:52:11

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-13T17:14:48-05:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3f9cf30b-243a-4e0c-8cb4-4738f3b88294'	System	13 Mar 2021 22:15:03
User entered 'No (N)'	System	13 Mar 2021 22:15:03

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-13T17:14:57-05:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3f9cf30b-243a-4e0c-8cb4-4738f3b88294'	System	13 Mar 2021 22:15:03
User entered 'No (N)'	System	13 Mar 2021 22:15:03

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-13T17:15:01-05:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '3f9cf30b-243a-4e0c-8cb4-4738f3b88294'	System	13 Mar 2021 22:15:03
User entered '13 Mar 2021 17:15:01'	System	13 Mar 2021 22:15:03

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-19T12:05:35-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4a9304f3-3672-496b-a8db-8c8f507ce980'	System	19 Mar 2021 16:11:45
User entered 'No (N)'	System	19 Mar 2021 16:11:45

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-19T12:05:37-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4a9304f3-3672-496b-a8db-8c8f507ce980'	System	19 Mar 2021 16:11:45
User entered 'No (N)'	System	19 Mar 2021 16:11:45

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-19T12:05:40-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '4a9304f3-3672-496b-a8db-8c8f507ce980'	System	19 Mar 2021 16:11:45
User entered '19 Mar 2021 12:05:40'	System	19 Mar 2021 16:11:45

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-02T12:00:25-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f86aa373-ef89-4e64-84b2-785aa545ded5'	System	02 Apr 2021 16:02:10
User entered 'No (N)'	System	02 Apr 2021 16:02:10

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-02T12:00:41-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f86aa373-ef89-4e64-84b2-785aa545ded5'	System	02 Apr 2021 16:02:10
User entered 'No (N)'	System	02 Apr 2021 16:02:10

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-02T12:00:43-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'f86aa373-ef89-4e64-84b2-785aa545ded5'	System	02 Apr 2021 16:02:10
User entered '02 Apr 2021 12:00:43'	System	02 Apr 2021 16:02:10

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-09T12:03:15-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '28adb86b-1a6d-4470-a1e6-cf467749b7b6'	System	09 Apr 2021 16:08:49
User entered 'No (N)'	System	09 Apr 2021 16:08:49

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-09T12:03:19-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '28adb86b-1a6d-4470-a1e6-cf467749b7b6'	System	09 Apr 2021 16:08:49
User entered 'No (N)'	System	09 Apr 2021 16:08:49

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-09T12:03:22-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '28adb86b-1a6d-4470-a1e6-cf467749b7b6'	System	09 Apr 2021 16:08:49
User entered '09 Apr 2021 12:03:22'	System	09 Apr 2021 16:08:49

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-14T09:06:04-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '10f0b389-6f09-4942-87d9-5a8bdf31a5c'	System	14 Apr 2021 13:06:12
User entered 'No (N)'	System	14 Apr 2021 13:06:12

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-14T09:06:07-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '10f0b389-6f09-4942-87d9-5a8bdf31a5c'	System	14 Apr 2021 13:06:12
User entered 'No (N)'	System	14 Apr 2021 13:06:12

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-14T09:06:10-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '10f0b389-6f09-4942-87d9-5a8bdf31a5c'	System	14 Apr 2021 13:06:12
User entered '14 Apr 2021 09:06:10'	System	14 Apr 2021 13:06:12

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-21T05:47:14-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '18242bca-bb29-46b5-8505-e567976c0293'	System	21 Apr 2021 09:47:23
User entered 'No (N)'	System	21 Apr 2021 09:47:23

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-21T05:47:18-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '18242bca-bb29-46b5-8505-e567976c0293'	System	21 Apr 2021 09:47:23
User entered 'No (N)'	System	21 Apr 2021 09:47:23

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-21T05:47:21-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '18242bca-bb29-46b5-8505-e567976c0293'	System	21 Apr 2021 09:47:23
User entered '21 Apr 2021 05:47:21'	System	21 Apr 2021 09:47:23

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-28T06:07:16-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5d3937e1-433e-4a64-8e5d-c19550c6f5bc'	System	29 Apr 2021 03:09:01
User entered 'No (N)'	System	29 Apr 2021 03:09:01

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

Have you been exposed to someone with 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 (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-28T06:07:18-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5d3937e1-433e-4a64-8e5d-c19550c6f5bc'	System	29 Apr 2021 03:09:01
User entered 'No (N)'	System	29 Apr 2021 03:09:01

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-04-28T06:07:21-04:00', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: '5d3937e1-433e-4a64-8e5d-c19550c6f5bc'	System	29 Apr 2021 03:09:01
User entered '28 Apr 2021 06:07:21'	System	29 Apr 2021 03:09:01

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 08:50:19

US3622032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:02:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:50:19
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 08:50:19

US3622032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:02:46

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 19:03:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-01T06:33:37', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'a9a6b5b3-cf11-453b-97e9-9117bc5cbce6'	System	05 Mar 2021 02:18:06
User entered 'No (N)'	System	05 Mar 2021 02:18:06

US3622032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 23:02:46

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:03:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (51148F00-727E-4492-A4C7-FAF41710509A)', Time: '2021-03-01T06:33:41', User OID: 'PatientReportedOutcome (US3622032)', ODM File OID: 'a9a6b5b3-cf11-453b-97e9-9117bc5cbce6' User entered '01 Mar 2021 06:33:41'	System	05 Mar 2021 02:18:06
	System	05 Mar 2021 02:18:06

US3622032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 18:53:51
User entered 'Yes (Y)'	Junlin Long	11 Nov 2020 13:09:30

US3622032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 18:53:51
User entered '10 Nov 2020'	Junlin Long (b) (4)	11 Nov 2020 13:09:30

US3622032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 18:53:51
User entered 'Contact Made (CONTACT MADE)'	Junlin Long	11 Nov 2020 13:09:30

US3622032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 18:53:51
User entered empty.	Junlin Long (b) (4)	11 Nov 2020 13:09:30

US3622032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 18:53:51
User entered 'Yes (Y)'	Junlin Long (b) (4)	11 Nov 2020 13:09:32

US3622032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:19:19
User entered 'I'	System	11 Nov 2020 13:09:32

US3622032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long (b) (4)	11 Dec 2020 18:25:17

US3622032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '11 Dec 2020'	Junlin Long (b) (4)	11 Dec 2020 18:25:17

US3622032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	11 Dec 2020 18:25:17

US3622032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	11 Dec 2020 18:25:17

US3622032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long (b) (4)	11 Dec 2020 18:25:21

US3622032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'I'	System	11 Dec 2020 18:25:21

US3622032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Yes (Y)'	Junlin Long	01 Feb 2021 15:34:57

US3622032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered '12 Jan 2021'	Junlin Long	01 Feb 2021 15:34:57

US3622032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Contact Made (CONTACT MADE)'	Junlin Long	01 Feb 2021 15:34:57

US3622032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered empty.	Junlin Long	01 Feb 2021 15:34:57

US3622032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Yes (Y)'	Junlin Long	01 Feb 2021 15:35:01

US3622032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'I'	System	01 Feb 2021 15:35:01

US3622032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Yes (Y)'	Junlin Long	09 Feb 2021 14:58:51

US3622032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered '9 Feb 2021'	Junlin Long	09 Feb 2021 14:58:51

US3622032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	09 Feb 2021 14:58:51

US3622032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered empty.	Junlin Long (b) (4)	09 Feb 2021 14:58:51

US3622032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Yes (Y)'	Junlin Long	09 Feb 2021 14:58:55

US3622032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'I'	System	09 Feb 2021 14:58:55

US3622032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Yes (Y)'	Junlin Long	15 Mar 2021 13:17:45

US3622032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '15 Mar 2021'	Junlin Long (b) (4)	15 Mar 2021 13:17:45

US3622032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	15 Mar 2021 13:17:45

US3622032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'VISIT4'	System	15 Mar 2021 13:17:45

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered 'Yes (Y)'	Junlin Long	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered '15 Mar 2021'	Junlin Long	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered '08:32'	Junlin Long	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered '15 Mar 2021 08:32'	System	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered '98.6' F	Junlin Long (b) (4)	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered 'Oral (Oral)'	Junlin Long (b) (4)	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered empty.	Junlin Long	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered '101'	Junlin Long (b) (4)	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'bpm'	System	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered '18'	Junlin Long	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'breaths/min'	System	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
User entered '92'	Junlin Long	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'mmHg'	System	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	01 Apr 2021 18:09:31
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) (b) (4), (b) (6)	30 Mar 2021 10:35:13
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 with 'ncs' (Site from System).	Junlin Long (b) (4) (b) (4)	29 Mar 2021 12:02:17
User opened query 'Diastolic Blood Pressure reported System 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).		29 Mar 2021 12:02:02
User entered '59'	Junlin Long (b) (4) (b) (4)	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'mmHg'	System	29 Mar 2021 12:02:02

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35

US3622032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35

US3622032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'No (N)'	Junlin Long	15 Mar 2021 13:17:53

US3622032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered empty.	Junlin Long (b) (4)	15 Mar 2021 13:17:53

US3622032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Mar 2021 13:18:03

US3622032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '15 Mar 2021'	Junlin Long (b) (4)	15 Mar 2021 13:18:03

US3622032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '08:50'	Junlin Long (b) (4)	15 Mar 2021 13:18:03

US3622032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered '15 Mar 2021 08:50'	System	15 Mar 2021 13:18:03

US3622032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Yes (Y)'	Junlin Long	15 Mar 2021 13:18:07

US3622032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:36:35
User entered 'I'	System	15 Mar 2021 13:18:07

US3622032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:22:19
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Apr 2021 15:53:34
	(b) (4)	

US3622032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:22:19
	(b) (4)	
User entered '12 Apr 2021'	Junlin Long (b) (4)	12 Apr 2021 15:53:34
	(b) (4)	

US3622032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:22:19
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Junlin Long (b) (4)	12 Apr 2021 15:53:34
	(b) (4)	

US3622032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:22:19
	(b) (4)	
User entered 'unable to contact; messages left'	Junlin Long (b) (4)	12 Apr 2021 15:53:34
	(b) (4)	

US3622032

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	16 Apr 2021 02:22:19
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Apr 2021 15:53:38
	(b) (4)	

US3622032

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 15:53:38

US3622032

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

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long	07 Jan 2021 18:36:55

US3622032

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

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long	07 Jan 2021 18:36:55

US3622032

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

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	07 Jan 2021 18:36:55

US3622032

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

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'UNBLND_DECIDE'	System	07 Jan 2021 18:36:55

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long	07 Jan 2021 18:37:04

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[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 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:06:59
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:51:50

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long	07 Jan 2021 18:37:04

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:06:59
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:51:50

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long	07 Jan 2021 18:37:04

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Placebo (Placebo)'	Junlin Long	07 Jan 2021 18:37:04

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:02:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Placebo (Placebo)'	(b) (4) Junlin Long (b) (4) (b) (4)	07 Jan 2021 18:37:04

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:02:36
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Placebo (Placebo)'	(b) (4) Junlin Long (b) (4) (b) (4)	07 Jan 2021 18:37:04

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long	07 Jan 2021 18:37:04

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '1'	System	07 Jan 2021 18:37:04

US3622032

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

Form: Unblinding

Generated On: 11 Aug 2021 23:02:46

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'I'	System	07 Jan 2021 18:37:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '64.8' in	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '103' lb	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '17.28212'	System	08 Jan 2021 10:59:04
DataPoint set to visible.	System	07 Jan 2021 18:37:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '64.8' in	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '103' lb	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '17.28212'	System	08 Jan 2021 10:59:04
DataPoint set to visible.	System	07 Jan 2021 18:37:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '12:37'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '7 Jan 2021 12:37'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '97.5' F	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Oral (Oral)'	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered empty.	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '97'	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'bpm'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '16'	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'breaths/min'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '105'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'mmHg'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '68'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'mmHg'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '64.8' in	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '103' lb	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:02:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '17.28212'	System	08 Jan 2021 10:59:04
DataPoint set to visible.	System	07 Jan 2021 18:37:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '14:06'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '7 Jan 2021 14:06'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '98.7' F	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Oral (Oral)'	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered empty.	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '92'	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'bpm'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '18'	Junlin Long (b) (4)	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'breaths/min'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '125'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'mmHg'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '70'	Junlin Long	08 Jan 2021 10:59:04

US3622032

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'mmHg'	System	08 Jan 2021 10:59:04

US3622032

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

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'No (N)'	Junlin Long	08 Jan 2021 10:59:12

US3622032

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

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered empty.	Junlin Long	08 Jan 2021 10:59:12

US3622032

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long	08 Jan 2021 10:59:29

US3622032

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long (b) (4)	08 Jan 2021 10:59:29

US3622032

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Urine (URINE)'	Junlin Long	08 Jan 2021 10:59:29

US3622032

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Negative (NEGATIVE)'	Junlin Long (b) (4)	08 Jan 2021 10:59:29

US3622032

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'No (N)'	Junlin Long	08 Jan 2021 10:59:29

US3622032

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered empty.	Junlin Long	08 Jan 2021 10:59:29

US3622032

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered empty.	Junlin Long	08 Jan 2021 10:59:29

US3622032

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered empty.	System	08 Jan 2021 10:59:29

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long	07 Jan 2021 18:37:22

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered empty.	Junlin Long (b) (4)	07 Jan 2021 18:37:22

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered empty.	Junlin Long	07 Jan 2021 18:37:22

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'mRNA-1273'	System	07 Jan 2021 18:37:22
DataPoint set to visible.	System	07 Jan 2021 18:37:04

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long	07 Jan 2021 18:37:22

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '13:34'	Junlin Long	07 Jan 2021 18:37:22

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '7 Jan 2021 13:34'	System	07 Jan 2021 18:37:22

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Left Arm (LEFT ARM)'	Junlin Long	07 Jan 2021 18:37:22

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'ONCE'	System	07 Jan 2021 18:37:22

US3622032

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

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'INTRAMUSCULAR'	System	07 Jan 2021 18:37:22

US3622032

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long (b) (4)	08 Jan 2021 10:59:43

US3622032

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long (b) (4)	08 Jan 2021 10:59:43

US3622032

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '12:59'	Junlin Long	08 Jan 2021 10:59:43

US3622032

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '7 Jan 2021 12:59'	System	08 Jan 2021 10:59:43

US3622032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long (b) (4)	08 Jan 2021 10:59:53

US3622032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '7 Jan 2021'	Junlin Long (b) (4)	08 Jan 2021 10:59:53

US3622032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:02:46

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered '12:55'	Junlin Long	08 Jan 2021 10:59:53

US3622032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered '7 Jan 2021 12:55'	System	08 Jan 2021 10:59:53

US3622032

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

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'Yes (Y)'	Junlin Long	08 Jan 2021 10:59:56

US3622032

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

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:30
User entered 'I'	System	08 Jan 2021 10:59:56

US3622032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:24
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'Yes (Y)'	Junlin Long	14 Jan 2021 17:47:16

US3622032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:24
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '14 Jan 2021'	Junlin Long	14 Jan 2021 17:47:16

US3622032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:24
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'Contact Made (CONTACT MADE)'	Junlin Long	14 Jan 2021 17:47:16

US3622032

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:24
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:47:16

US3622032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:24
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'Yes (Y)'	Junlin Long	14 Jan 2021 17:47:20

US3622032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:24
User entered 'I'	System	14 Jan 2021 17:47:20

US3622032

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:02:24
User entered '1'	System	14 Jan 2021 17:47:20
DataPoint set to visible.	System	14 Jan 2021 17:47:20

US3622032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Yes (Y)'	Junlin Long	05 Feb 2021 15:05:21

US3622032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered '4 Feb 2021'	Junlin Long	05 Feb 2021 15:05:21

US3622032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[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 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Clinic (Clinic)'	Junlin Long	05 Feb 2021 15:05:21

US3622032

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'OLD29'	System	05 Feb 2021 15:05:21

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4)	08 Feb 2021 14:41:12
	(b) (4)	

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered 'Yes (Y)'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User closed query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:35:41
Query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile' answered with 'Participant came in for OL-D29 on 04FEB2021. Their pregnancy test result was positive, so they did not receive the study vaccine on that day. PI submitted EPIP. Based on sponsor's feedback, participant came back on 08FEB2021 and got the study vaccine.' (Site from DM).	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:38:34
User opened query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:51:48
Query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile.' canceled (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:43:24
User opened query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:35:32
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Apr 2021 14:33:15
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Feb 2021 13:12:31
User entered '8 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 13:12:31
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Feb 2021 13:08:54
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Feb 2021 13:08:54
User entered '4 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 13:08:54

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Amendment Manager: User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:56:15
Comment added 'participant's pregnancy test was positive during the visit on 04FEB2021. epip submitted by pi on 04FEB2021; based on feedback, pi decided to vaccinate this participant on 08FEB2021.'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:42:36
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Feb 2021 14:41:12
User entered '8 Feb 2021'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '08:28'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered '8 Feb 2021 08:28'	System	24 Feb 2021 13:12:31
User entered '4 Feb 2021 08:28'	System	24 Feb 2021 13:08:54
User entered '8 Feb 2021 08:28'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '98.4' F	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered 'Oral (Oral)'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered empty.	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '96'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'bpm'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '16'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'breaths/min'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '91'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'mmHg'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '69'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:02:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'mmHg'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered 'Yes (Y)'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User closed query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:35:48
Query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile ' answered with 'Participant came in for OL-D29 on 04FEB2021. Their pregnancy test result was positive, so they did not receive the study vaccine on that day. PI submitted EPIP. Based on sponsor's feedback, participant came back on 08FEB2021 and got the study vaccine.' (Site from DM).	Junlin Long (b) (4) (b) (4)	16 Apr 2021 12:38:53
User opened query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:57:58
Query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile.' canceled (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:57:46
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Apr 2021 14:36:20
User opened query 'Per CDM: 'The Date of assessment' is not equal to 'Visit Date'. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:36:16
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Apr 2021 14:36:04
Amendment Manager: User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:56:15
Comment added 'participant's pregnancy test was positive during the visit on 04FEB2021. epip submitted by pi on 04FEB2021; based on feedback, pi decided to vaccinate this participant on 08FEB2021.'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:42:49

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Feb 2021 14:41:12
User entered '8 Feb 2021'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '09:27'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered '8 Feb 2021 09:27'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '98.6' F	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered 'Oral (Oral)'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered empty.	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '96'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'bpm'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '16'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'breaths/min'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '95'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'mmHg'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	26 Apr 2021 20:38:11
User entered '65'	Junlin Long	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:02:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'mmHg'	System	08 Feb 2021 14:41:12

US3622032

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'No (N)'	Junlin Long	08 Feb 2021 14:42:56

US3622032

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered empty.	Junlin Long	08 Feb 2021 14:42:56

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Yes (Y)'	Junlin Long	05 Feb 2021 15:07:06

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered '4 Feb 2021'	Junlin Long	05 Feb 2021 15:07:06

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Urine (URINE)'	Junlin Long	05 Feb 2021 15:07:06

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 12:45:07
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'confirmed that pregnancy test was positive; pi will submit the pregnancy form.' (Site from System).	Junlin Long (b) (4) (b) (4)	08 Feb 2021 13:59:57
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	05 Feb 2021 15:07:06
User entered 'Positive (POSITIVE)'	Junlin Long (b) (4) (b) (4)	05 Feb 2021 15:07:06

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'No (N)'	Junlin Long	05 Feb 2021 15:07:06

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered empty.	Junlin Long	05 Feb 2021 15:07:06

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered empty.	Junlin Long	05 Feb 2021 15:07:06

US3622032

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered empty.	System	05 Feb 2021 15:07:06

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User closed query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject has positive results. Please review and update or explain otherwise.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 12:44:34
Query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject had positive results. Please review and update or explain otherwise.' answered with 'epip submitted; based on the feedback, pi decided to vaccinate this participant.' (Site from System).	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:01:25
User opened query 'Was study treatment given is "Yes", however Pregnancy Form indicates subject had positive results. Please review and update or explain otherwise.' (Site from System).	System	08 Feb 2021 14:00:17
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered empty.	Junlin Long	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered empty.	Junlin Long (b) (4)	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'mRNA-1273'	System	08 Feb 2021 14:00:17
DataPoint set to visible.	System	14 Jan 2021 17:47:20

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 04:33:18
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'participant's pregnancy test was positive during the visit on 04FEB2021. epip submitted by pi on 04FEB2021; based on feedback, pi decided to vaccinate this participant on 08FEB2021.' (Site from System).	Junlin Long (b) (4) (b) (4)	18 Feb 2021 14:46:18
Amendment Manager: User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:56:15
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 12:39:24
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'participant's pregnancy test was positive during the visit on 04FEB2021. epip submitted by pi on 04FEB2021; based on feedback, pi decided to vaccinate this participant on 08FEB2021.' (Site from System).	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:03:09
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	08 Feb 2021 14:00:17
User entered '8 Feb 2021'	Junlin Long (b) (4) (b) (4)	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered '08:54'	Junlin Long	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered '8 Feb 2021 08:54'	System	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Left Arm (LEFT ARM)'	Junlin Long	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'ONCE'	System	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:02:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 14:00:17

US3622032

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Yes (Y)'	Junlin Long	08 Feb 2021 14:43:03

US3622032

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:59
User entered 'I'	System	08 Feb 2021 14:43:03

US3622032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:04:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:21:00

US3622032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:04:18
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:21:00

US3622032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:04:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:21:00

US3622032

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:02:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:04:18
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:21:00

US3622032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:04:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 15:21:24

US3622032

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:02:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:05
User entered '1'	System	15 Feb 2021 15:21:24

US3622032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Yes (Y)'	Junlin Long	15 Mar 2021 13:18:17

US3622032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '15 Mar 2021'	Junlin Long	15 Mar 2021 13:18:17

US3622032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	15 Mar 2021 13:18:17

US3622032

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:02:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User entered 'OLD57'	System	15 Mar 2021 13:18:17

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Yes (Y)'	Junlin Long	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '15 Mar 2021'	Junlin Long	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '08:32'	Junlin Long	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User entered '15 Mar 2021 08:32'	System	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '98.6' F	Junlin Long (b) (4)	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Oral (Oral)'	Junlin Long	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered empty.	Junlin Long	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '101'	Junlin Long	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User entered 'bpm'	System	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '18'	Junlin Long	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User entered 'breaths/min'	System	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '92'	Junlin Long	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User entered 'mmHg'	System	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
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) (b) (4), (b) (6)	16 Mar 2021 10:20:03
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 with 'ncs' (Site from System).	Junlin Long (b) (4) (b) (4)	15 Mar 2021 13:20:52
User opened query 'Diastolic Blood Pressure reported System 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).		15 Mar 2021 13:18:43
User entered '59'	Junlin Long (b) (4) (b) (4)	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User entered 'mmHg'	System	15 Mar 2021 13:18:43

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11

US3622032

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:02:46

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 04:41:11

US3622032

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'No (N)'	Junlin Long	15 Mar 2021 13:18:57

US3622032

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:02:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered empty.	Junlin Long	15 Mar 2021 13:18:57

US3622032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered 'Yes (Y)'	Junlin Long	15 Mar 2021 13:19:06

US3622032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '15 Mar 2021'	Junlin Long (b) (4)	15 Mar 2021 13:19:06

US3622032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
User entered '08:50'	Junlin Long (b) (4)	15 Mar 2021 13:19:06

US3622032

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:41:11
User entered '15 Mar 2021 08:50'	System	15 Mar 2021 13:19:06

US3622032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 23:02:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:19
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	14 Jan 2021 17:47:41
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Junlin Long (b) (4)	14 Jan 2021 17:47:41
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	14 Jan 2021 14:57:04
User entered 'No (N)'	(b) (4)	
	Junlin Long (b) (4)	14 Dec 2020 14:00:29
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Jan 2021 17:51:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 17:51:06
Data point term sent to Coder	System	14 Jan 2021 17:49:28
User entered 'left arm injection site pain'	Junlin Long (b) (4) (b) (4)	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'No (N)'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'No (N)'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'No (N)'	Junlin Long (b) (4)	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '7 Jan 2021'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '16:00'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User entered '7 Jan 2021 16:00'	System	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'No (N)'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '9 Jan 2021'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 10:04:13
Query 'Data is required. Please provide.' answered with 'not required' (Site from System).	Junlin Long (b) (4) (b) (4)	14 Jan 2021 17:48:41
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Jan 2021 17:48:29
User entered empty.	Junlin Long (b) (4) (b) (4)	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User entered empty.	System	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'No (N)'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'Related (RELATED)'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'Related (RELATED)'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'None (NONE)'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'I'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Junlin Long (b) (4)	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long (b) (4)	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User entered '0'	System	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18
User entered '0'	System	14 Jan 2021 17:48:29

US3622032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:02:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:18

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Feb 2021 18:23:51
User entered		
'USA-US085-2021-mRNA-1273-P301000011'	System	08 Feb 2021 18:23:46
User entered 'New'	(b) (4), (b) (6)	08 Feb 2021 18:23:46

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Pregnancy, LLT: Pregnancy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 15:02:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 15:02:42
	(b) (4)	
Data point term sent to Coder	System	05 Feb 2021 15:02:05
User entered 'pregnancy'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '18 Jan 2021'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 15:01:13

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 15:01:13

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Junlin Long (b) (4) (b) (4)	05 Feb 2021 15:01:13

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'I'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide an update regarding the outcome of the pregnancy. Please provide details regarding the delivery and infant details by completing the relevant sections of the Pregnancy Report Form.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 21:54:51
User opened query 'PV Query: Please provide an update regarding the outcome of the pregnancy. Please provide details regarding the delivery and infant details by completing the relevant sections of the Pregnancy Report Form.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 21:08:21
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	05 Feb 2021 15:01:13

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:01:13
	(b) (4)	

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 15:01:13

US3622032

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:02:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 15:01:13

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:02:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:14:19
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:07:18

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE, PRODUCTSYNONYM: PROGESTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:09:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:09:48
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	22 Aug 2020 17:52:06
Data point term sent to Coder	System	18 Aug 2020 16:25:10
User entered 'progestin'	(b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'birth control'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:53:23
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 06:08:26
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 14:29:11
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 14:28:29
User entered 'Unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:28:29
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:55:58
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:53:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	07 Apr 2021 14:29:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Apr 2021 14:29:44
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:29:44
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Apr 2021 14:28:29
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 14:28:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:28:29
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:53:23
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:29:44
User entered 'unknown' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 14:29:44
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:57:51
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 16:24:26
User entered 'un UNK 2020'	(b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:49:43
Signature has been broken.	Junlin Long	04 Mar 2021 17:06:59
User entered 'No (N)' reason for change: New Information	Junlin Long	04 Mar 2021 17:06:59
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'Yes (Y)'		18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:49:43
Signature has been broken.	Junlin Long (b) (4)	04 Mar 2021 17:06:59
User entered 'un Dec 2020' reason for change: New Information	Junlin Long (b) (4)	04 Mar 2021 17:06:59
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User signature succeeded.	Susanne Doblecki-Lewis	22 Aug 2020 17:52:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User entered '1'	System	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User entered '1'	System	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:20:02
User entered '804 (804)'	System	18 Aug 2020 16:24:26

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 17:51:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 17:51:08
	(b) (4)	
Data point term sent to Coder	System	14 Jan 2021 17:50:28
User entered 'multivitamin'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered 'vitamin supplement'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered '1'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered 'tablet (TABLET)'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered 'once daily (QD)'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered 'un Sep 2020'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	14 Jan 2021 17:49:34
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 17:49:34

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 17:49:34

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Jan 2021 17:49:34

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Jan 2021 17:51:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 17:51:07
Data point term sent to Coder	System	14 Jan 2021 17:50:28
User entered 'ibuprofen'	Junlin Long (b) (4) (b) (4)	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'No (N)'	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'left arm injection site pain'	Junlin Long (b) (4)	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '200'	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'mg (mg)'	Junlin Long (b) (4)	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'as needed (PRN)'	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered empty.	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '7 Jan 2021'	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '0'	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'No (N)'	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered '9 Jan 2021'	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 14:47:31
User entered 'No (N)'	Junlin Long	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User entered empty.	System	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User entered empty.	System	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:04:16
User entered empty.	System	14 Jan 2021 17:50:09

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 06:09:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 06:09:48
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	12 Feb 2021 13:59:05
Data point term sent to Coder	System	05 Feb 2021 15:05:06
User entered 'prenatal vitamin (alive)'	Junlin Long (b) (4) (b) (4)	05 Feb 2021 15:04:07

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'pregnancy supplement'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'unknown'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Other (OTHER)'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'unknown'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'twice daily (BID)'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '18 Jan 2021'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	05 Feb 2021 15:04:07
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Feb 2021 15:04:07

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 15:04:07

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 15:04:07

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 13:33:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 13:33:03
	(b) (4)	
Data point term sent to Coder	System	15 Mar 2021 13:32:07
User entered 'loratadine'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered 'seasonal allergies'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered '10'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered 'as needed (PRN)'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered '22 Feb 2021'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	19 Mar 2021 14:00:52
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	15 Mar 2021 13:31:54
	(b) (4)	

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 13:31:54

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 13:31:54

US3622032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:02:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Mar 2021 13:31:54

US3622032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:02:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	09 Feb 2021 14:59:09
	(b) (4)	

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'USA-US085-2021-MRNA-1273-P301000011'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'Susanne'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'Doblecki-Lewis'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered '1120 NW 14th Street'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'Miami'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'FL'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered '33136'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'US'	(b) (4) System	08 Feb 2021 18:24:34

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'I'	(b) (4) System	08 Feb 2021 18:24:34

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'USA-US085-2021-MRNA-1273-P301000011'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

Serious

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'No (N)'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'Susanne'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'Doblecki-Lewis'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered '1120 NW 14th Street'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'Miami'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered 'FL'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:28
User entered '33136'	System	08 Feb 2021 18:23:46

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'US'	(b) (4) System	08 Feb 2021 18:24:34

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 23:02:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'I'	(b) (4) System	08 Feb 2021 18:24:34

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:02:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
	(b) (4)	
User entered '08/Feb/2021 18:24'	System	08 Feb 2021 18:24:34

US3622032

Folder: SAE USA-US085-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 23:02:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 13:59:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:24:34