

US3622282 (Prod: University of Miami)

Generated By: KC Joubran

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US3622282

Form: Participant Creation

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

[Participant ID](#)

US3622282

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

US3622282

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3622282

Folder: Screening

Form: Demographics

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☒
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Condition	HIV INFECTION
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Condition	ASTHMA (SEVERE)
Start date (dd MMM yyyy)	UN UNK 1971
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1971
Start Year (derived)	1971
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Condition	POST-TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622282

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Condition	PARANOIA
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622282

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Condition	NERVE DAMAGE (NEUROPATHY)
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Condition	RIGHT ANKLE SURGERY
Start date (dd MMM yyyy)	3 OCT 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	3 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2020
Start Year (derived)	2020
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:51 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 08:51
Height (<i>xxx.x</i>)	62 in
Weight (<i>xxx.x</i>)	185 lb
BMI (<i>xxx.x</i>)	33.90769 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622282

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Date of assessment (dd MMM yyyy) 21 OCT 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) UN UNK 2013

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

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

CAR DETAILING

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Oct 2020 15:19:19

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

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

What was the participant's randomization number? 147141

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☒ No ☐

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m²) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☒ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 08:51
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:25
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3622282

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:52 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 10:52

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

09:00 (24 HR)

Collection date and time (derived)

21 OCT 2020 09:00

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Collection date (dd MMM yyyy)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:07	21 OCT 2020 09:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

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 21 OCT 2020 11:33

PC Open Date & Time 21 OCT 2020 11:12

PC Close Date & Time 21 OCT 2020 13:42

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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 94.9 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 21 OCT 2020 17:23

PC Open Date & Time 21 OCT 2020 14:37

PC Close Date & Time 22 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

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 101.0 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 22 OCT 2020 17:41

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

24 OCT 2020 10:46

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 19:24

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 18:58

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:55

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

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

26 OCT 2020 19:08

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:55

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

99.0 °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

27 OCT 2020 19:00

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 11:34

PC Open Date & Time

21 OCT 2020 11:12

PC Close Date & Time

21 OCT 2020 13:42

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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

21 OCT 2020 17:25

PC Open Date & Time

21 OCT 2020 14:37

PC Close Date & Time

22 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

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

22 OCT 2020 17:42

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

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

24 OCT 2020 10:46

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

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

24 OCT 2020 19:25

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

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

25 OCT 2020 18:58

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

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

26 OCT 2020 19:08

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

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

27 OCT 2020 19:01

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 11:35
PC Open Date & Time	21 OCT 2020 11:12
PC Close Date & Time	21 OCT 2020 13:42

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 17:28
PC Open Date & Time	21 OCT 2020 14:37
PC Close Date & Time	22 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

Yes ☐	
PC Time stamp	22 OCT 2020 17:44
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

Yes ☐	
PC Time stamp	24 OCT 2020 10:47
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

Yes ☐	
PC Time stamp	24 OCT 2020 19:25
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

Yes ☐	
PC Time stamp	25 OCT 2020 18:58
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

Yes ☐	
PC Time stamp	26 OCT 2020 19:09
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

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 ☒

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

Yes ☐	
PC Time stamp	27 OCT 2020 19:01
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3622282

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622282

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622282

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Nov 2020 19:18:24

Generated On: 26 Nov 2020 11:08:55

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

US3622282

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Nov 2020 19:18:24

Generated On: 26 Nov 2020 11:08:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622282

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

Was this visit performed?	Yes ☐
	No ☐

Visit date (dd MMM yyyy)	

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

Folder OID	

US3622282

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:55

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.

US3622282

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

Was study treatment given? Yes ☐
No ☐

If No, reason not given

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

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

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3622282

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:55

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3622282

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:55

Collection date (dd MMM yyyy)			
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3622282

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

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12 APR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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21 JUN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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28 JUN 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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01 JUL 2022 00:01

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05 JUL 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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08 JUL 2022 00:01

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12 JUL 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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19 JUL 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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09 AUG 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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23 AUG 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

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30 AUG 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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06 SEP 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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13 SEP 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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27 SEP 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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30 SEP 2022 00:01

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04 OCT 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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07 OCT 2022 00:01

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11 OCT 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

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18 OCT 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

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25 OCT 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

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US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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08 NOV 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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11 NOV 2022 00:01

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15 NOV 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

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22 NOV 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

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29 NOV 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

[Patient Cloud Close Date & Time](#)

20 DEC 2022 23:59

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2022 23:59

US3622282

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:08:55

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3622282

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:08:55

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3622282

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

AEID	USA-US085-2020-MRNA-1273-P30 1000002
Adverse event	FOOT/ANKLE SURGERY
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)	05 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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	True
Hospital Admission Date (dd MMM yyyy)	05 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☒
Number of Days in ICU	
v6.020 DTW (1102)	291 of 1400

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☒
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

PARTICIPANT MISSED HER
VISIT 2 APPOINTMENT TODAY.
ATTEMPTED TO CONTACT
MULTIPLE TIMES TODAY.
CALLED EMERGENCY
CONTACT AND HE STATED SHE
WAS IN THE HOSPITAL FOR
ABOUT 1.5 WEEKS DUE TO
FOOT/ANKLE SURGERY.
CONTACT PERSON WITH
LIMITED KNOWLEDGE OF
EVENTS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Oct 2020 15:19:19

Generated On: 26 Nov 2020 11:08:55

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

Yes ☒

No ☐

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

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication TRIUMEQ

Prophylaxis Yes ☐
No ☒

Indication HIV

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 ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication LATUDA

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER

Dose per administration 40

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 ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication DEPAKOTE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication PARANOIA

Dose per administration 400

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 ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

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 ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication RIGHT ANKLE PAIN

Dose per administration 800

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 ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication LYRICA

Prophylaxis Yes ☐
No ☒

Indication NERVE DAMAGE

Dose per administration 150

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 ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication XARELTO

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR DEEP VEIN
THROMBOSIS

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 ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 90

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

EVERY 4 TO 6 HOURS AS
NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication DUONEB (IPRATROPIUM BROMIDE/ALBUTEROL)

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 0.5/0.3

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

EVERY 8 HOURS AS NEEDED

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication	TYLENOL
Prophylaxis	Yes ☒ No ☐
Indication	RIGHT ANKLE PAIN
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

Name of Medication NEOSPORIN (BACITRACIN,
NEOMYCIN AND POLYMYXIN
B)

Prophylaxis Yes ☒
No ☐

Indication RIGHT ANKLE PAIN

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 ☐

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US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 10 Nov 2020 16:52:09

Generated On: 26 Nov 2020 11:08:55

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3622282

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:08:55

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3622282

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:08:55

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3622282

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:08:55

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 ☐

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:55

SAEID	USA-US085-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	19/NOV/2020 18:59
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

US3622282 (Prod: University of Miami)

US3622282

Form: Participant Creation

Generated On: 26 Nov 2020 11:08:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered 'US3622282'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:29

US3622282

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 14:59:29
	(b) (4)	

US3622282

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 OCT 2020'	RWS_ENDPOINT	21 Oct 2020 14:13:30
	ENDPOINT (b) (4)	

US3622282

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	21 Oct 2020 14:59:29
	(b) (4)	

US3622282

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Oct 2020 14:59:29

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:31

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Age](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '51'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Oct 2020 17:06:53

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '51'	System	21 Oct 2020 14:59:51

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Sex](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Female (F)'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Ethnicity](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[White](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '1'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Black](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Asian](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[If race is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:08:55

[Not reported](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:06:53
	(b) (4)	

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 14:59:51
	(b) (4)	

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	21 Oct 2020 14:59:51

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 14:59:51

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

[Protocol Version](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Amendment 4 (4)'	Junlin Long (b) (4)	21 Oct 2020 14:59:51
	(b) (4)	

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 14:59:51
	(b) (4)	

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 14:59:51
	(b) (4)	

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 14:59:51
	(b) (4)	

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 14:59:51
	(b) (4)	

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	RWS_ENDPOINT	21 Oct 2020 14:13:30
	ENDPOINT (b) (4)	

US3622282

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:08:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:59:56

US3622282

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 14:59:56
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:08:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:07:09
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: HIV infection - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:08:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:08:44
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:07:50
User entered 'hiv infection'	Junlin Long (b) (4)	21 Oct 2020 17:07:33
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 1997'	Junlin Long (b) (4)	21 Oct 2020 17:07:33
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:07:33
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:07:33
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:07:33
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:07:33
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	21 Oct 2020 17:07:33

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '1997'	System	21 Oct 2020 17:07:33

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:07:33

US3622282

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:07:33

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:34:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 22:34:37
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:08:51
User entered 'asthma (severe)'	Junlin Long (b) (4)	21 Oct 2020 17:08:37
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 1971'	Junlin Long (b) (4)	21 Oct 2020 17:08:37
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:08:37
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:08:37
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:08:37
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:08:37
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Jan 1971'	System	21 Oct 2020 17:08:37

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '1971'	System	21 Oct 2020 17:08:37

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:08:37

US3622282

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:08:37

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:10:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:10:33
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:09:52
User entered 'bipolar disorder'	Junlin Long (b) (4)	21 Oct 2020 17:09:03
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 1985'	Junlin Long (b) (4)	21 Oct 2020 17:09:03
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:09:03
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:09:03
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:09:03
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:09:03
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	21 Oct 2020 17:09:03

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '1985'	System	21 Oct 2020 17:09:03

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:09:03

US3622282

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:09:03

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:10:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:10:33
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:09:53
User entered 'anxiety'	Junlin Long (b) (4)	21 Oct 2020 17:09:52
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 1985'	Junlin Long (b) (4)	21 Oct 2020 17:09:52
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:09:52
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:09:52
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:09:52
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:09:52
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	21 Oct 2020 17:09:52

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '1985'	System	21 Oct 2020 17:09:52

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:09:52

US3622282

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:09:52

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:11:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:11:45
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:10:55
User entered 'Post-traumatic stress disorder'	Junlin Long (b) (4)	21 Oct 2020 17:10:25
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 1985'	Junlin Long (b) (4)	21 Oct 2020 17:10:25
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:10:25
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:10:25
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:10:25
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:10:25
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	21 Oct 2020 17:10:25

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '1985'	System	21 Oct 2020 17:10:25

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:10:25

US3622282

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:10:25

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Personality disorders and disturbances in behaviour, HLT: Behaviour and socialisation disturbances, PT: Paranoia, LLT: Paranoia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:11:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:11:46
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:10:55
User entered 'paranoia'	Junlin Long (b) (4)	21 Oct 2020 17:10:40
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 1985'	Junlin Long (b) (4)	21 Oct 2020 17:10:40
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:10:40
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:10:40
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:10:40
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:10:40
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	21 Oct 2020 17:10:40

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '1985'	System	21 Oct 2020 17:10:40

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:10:40

US3622282

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:10:40

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Nerve injuries NEC, PT: Nerve injury, LLT: Nerve damage - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 08:39:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 08:39:10
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	24 Oct 2020 15:19:20
Data point term sent to Coder	System	21 Oct 2020 17:11:57
User entered 'nerve damage (neuropathy)'	Junlin Long (b) (4)	21 Oct 2020 17:11:17
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2001'	Junlin Long (b) (4)	21 Oct 2020 17:11:17
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:11:17
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:11:17
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:11:17
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:11:17
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	21 Oct 2020 17:11:17

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '2001'	System	21 Oct 2020 17:11:17

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:11:17

US3622282

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:11:17

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle operation, LLT: Ankle operation - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:12:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 17:12:36
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:12:00
User entered 'right ankle surgery'	Junlin Long (b) (4)	21 Oct 2020 17:11:49
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '3 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:11:49
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:11:49
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:11:49
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '3 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:11:49
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:11:49
	(b) (4)	

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	21 Oct 2020 17:11:49

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 17:11:49

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	21 Oct 2020 17:11:49

US3622282

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Oct 2020 17:11:49

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '08:51'	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 08:51'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '62' in	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	
DataPoint set to visible.	System	21 Oct 2020 14:59:56

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '185' lb	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	
DataPoint set to visible.	System	21 Oct 2020 14:59:56

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '33.90769'	System	21 Oct 2020 17:12:58
DataPoint set to visible.	System	21 Oct 2020 14:59:56

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	21 Oct 2020 17:12:58
DataPoint set to visible.	System	21 Oct 2020 14:59:56

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Other (Other)'	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:12:58
	(b) (4)	

US3622282

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:08:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 17:12:58

US3622282

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:13:08
	(b) (4)	

US3622282

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:13:08
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Surgically sterile (SURGICALLY STERILE)'	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:55

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2013'	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:55

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:08:55

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:13:55
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

[Specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'car detailing'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

No Risk Identified

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '1'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

[Other](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:08:55

[Specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:14:31
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 15:00:10
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 15:00:10
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	21 Oct 2020 15:00:10
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:08:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Oct 2020 15:00:10

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 OCT 2020'	RWS_ENDPOINT	21 Oct 2020 14:13:32
	ENDPOINT (b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '147141'	RWS_ENDPOINT	21 Oct 2020 14:13:32
	ENDPOINT (b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 14:13:32

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:14:54
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:54
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:54
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:54
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

[Liver Disease](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:54
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
Signature has been broken.	Junlin Long (b) (4)	28 Oct 2020 16:13:08
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Junlin Long (b) (4)	28 Oct 2020 16:13:08
	(b) (4)	
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:14:54
	(b) (4)	
DataPoint set to visible.	System	21 Oct 2020 14:59:51

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:55

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:55

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:55

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:55

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '08:51'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 08:51'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '97.9' F	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (Oral)'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '103'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '16'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '123'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '68'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:08:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:55

[Height](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:08:55

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered missing code ND - Not Done.	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '11:25'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:25'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '98.8' F	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (Oral)'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '103'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '20'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '121'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '67'	Junlin Long (b) (4)	21 Oct 2020 17:15:49
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:08:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 17:15:49

US3622282

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:15:52
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:08:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:15:52
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 15:00:28
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 15:00:28
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 15:00:28
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 15:00:28
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '10:52'	Junlin Long (b) (4)	21 Oct 2020 15:00:28
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 10:52'	System	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	21 Oct 2020 15:00:28
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:08:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 15:00:28

US3622282

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:16:05
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:16:05
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '09:00'	Junlin Long (b) (4)	21 Oct 2020 17:16:05
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 09:00'	System	21 Oct 2020 17:16:05

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:08:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '21 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:16:31
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4)	21 Oct 2020 17:16:31

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:16:31
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '09:07'	Junlin Long (b) (4)	21 Oct 2020 17:16:31
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '21 Oct 2020 09:07'	System	21 Oct 2020 17:16:31

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:16:31

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:16:31
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:16:31
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:16:31

US3622282

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:16:35
	(b) (4)	

US3622282

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:16:35

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:33:19', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1d7bf1a1-d78c-4d64-8cee-e7d74e34bf1b' User entered 'Yes (Y)'	System	21 Oct 2020 15:33:55
	System	21 Oct 2020 15:33:55

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:33:32', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1d7bf1a1-d78c-4d64-8cee-e7d74e34bf1b' User entered '98.8'	System	21 Oct 2020 15:33:55
	System	21 Oct 2020 15:33:55

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:33:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1d7bf1a1-d78c-4d64-8cee-e7d74e34bf1b'	System	21 Oct 2020 15:33:55
User entered 'No (N)'	System	21 Oct 2020 15:33:55

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:33:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1d7bf1a1-d78c-4d64-8cee-e7d74e34bf1b' User entered '21 Oct 2020 11:33'	System	21 Oct 2020 15:33:55
	System	21 Oct 2020 15:33:55

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:12'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 13:42'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:21:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1'	System	21 Oct 2020 21:23:41
User entered 'Yes (Y)'	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:22:40', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1'	System	21 Oct 2020 21:23:41
User entered '94.9'	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:22:49', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1'	System	21 Oct 2020 21:23:41
User entered 'Yes (Y)'	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:23:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1'	System	21 Oct 2020 21:23:41
User entered '1'	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:23:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1'	System	21 Oct 2020 21:23:41
User entered '0'	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:23:38', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '1f8684fb-7d9a-4555-9683-a56dc02cd8f1'	System	21 Oct 2020 21:23:41
User entered '21 Oct 2020 17:23'	System	21 Oct 2020 21:23:41

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 14:37'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 2'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:41:01', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0'	System	22 Oct 2020 21:41:21
User entered 'Yes (Y)'	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:40:15', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0' User entered '101.0'	System	22 Oct 2020 21:41:21
	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:40:30', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0'	System	22 Oct 2020 21:41:21
User entered 'Yes (Y)'	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:40:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0'	System	22 Oct 2020 21:41:21
User entered '1'	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:40:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0' User entered '0'	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:41:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ee88625a-fddb-42ec-8339-abbacca01fe0'	System	22 Oct 2020 21:41:21
User entered '22 Oct 2020 17:41'	System	22 Oct 2020 21:41:21

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 3'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:45:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bd02fcad-f396-4d42-b136-a7702667b1c6'	System	24 Oct 2020 15:24:51
User entered 'Yes (Y)'	System	24 Oct 2020 15:24:51

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:45:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bd02fcad-f396-4d42-b136-a7702667b1c6' User entered '97.3'	System	24 Oct 2020 15:24:51

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:45:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bd02fcad-f396-4d42-b136-a7702667b1c6'	System	24 Oct 2020 15:24:51
User entered 'No (N)'	System	24 Oct 2020 15:24:51

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bd02fcad-f396-4d42-b136-a7702667b1c6' User entered '24 Oct 2020 10:46'	System	24 Oct 2020 15:24:51
	System	24 Oct 2020 15:24:51

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 4'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:24:36', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '16bbb2f2-6baa-4297-89fd-53e3fc449d3d'	System	24 Oct 2020 23:24:59
User entered 'Yes (Y)'	System	24 Oct 2020 23:24:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:24:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '16bbb2f2-6baa-4297-89fd-53e3fc449d3d' User entered '98.0'	System	24 Oct 2020 23:24:59
	System	24 Oct 2020 23:24:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:24:47', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '16bbb2f2-6baa-4297-89fd-53e3fc449d3d'	System	24 Oct 2020 23:24:59
User entered 'No (N)'	System	24 Oct 2020 23:24:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:24:54', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '16bbb2f2-6baa-4297-89fd-53e3fc449d3d' User entered '24 Oct 2020 19:24'	System	24 Oct 2020 23:24:59
	System	24 Oct 2020 23:24:59

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 5'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:57:47', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'eb736ed9-796b-4776-be53-fb3f21ca2e11'	System	25 Oct 2020 22:58:06
User entered 'Yes (Y)'	System	25 Oct 2020 22:58:06

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:57:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'eb736ed9-796b-4776-be53-fb3f21ca2e11'	System	25 Oct 2020 22:58:06
User entered '98.0'	System	25 Oct 2020 22:58:06

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:57:56', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'eb736ed9-796b-4776-be53-fb3f21ca2e11'	System	25 Oct 2020 22:58:06
User entered 'No (N)'	System	25 Oct 2020 22:58:06

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:03', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'eb736ed9-796b-4776-be53-fb3f21ca2e11'	System	25 Oct 2020 22:58:06
User entered '25 Oct 2020 18:58'	System	25 Oct 2020 22:58:06

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 6'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '354467f4-fb6d-4609-b585-10c0638322e9' User entered 'Yes (Y)'	System	26 Oct 2020 23:08:29
	System	26 Oct 2020 23:08:29

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '354467f4-fb6d-4609-b585-10c0638322e9' User entered '99.2'	System	26 Oct 2020 23:08:29
	System	26 Oct 2020 23:08:29

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:16', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '354467f4-fb6d-4609-b585-10c0638322e9'	System	26 Oct 2020 23:08:29
User entered 'No (N)'	System	26 Oct 2020 23:08:29

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '354467f4-fb6d-4609-b585-10c0638322e9' User entered '26 Oct 2020 19:08'	System	26 Oct 2020 23:08:29
	System	26 Oct 2020 23:08:29

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 7'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:00:38', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '9acdf536-bef3-4792-8059-78e42626d07f'	System	27 Oct 2020 23:00:56
User entered 'Yes (Y)'	System	27 Oct 2020 23:00:56

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:00:44', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '9acdf536-bef3-4792-8059-78e42626d07f' User entered '99.0'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:00:48', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '9acdf536-bef3-4792-8059-78e42626d07f' User entered 'No (N)'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:00:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '9acdf536-bef3-4792-8059-78e42626d07f' User entered '27 Oct 2020 19:00'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:23', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6'	System	21 Oct 2020 15:34:58
User entered 'None (1)'	System	21 Oct 2020 15:34:58

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:35', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6'	System	21 Oct 2020 15:34:58
User entered 'No (N)'	System	21 Oct 2020 15:34:58

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6'	System	21 Oct 2020 15:34:58
User entered 'No (N)'	System	21 Oct 2020 15:34:58

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:45', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6'	System	21 Oct 2020 15:34:58
User entered 'None (1)'	System	21 Oct 2020 15:34:58

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:34:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd8c4ca70-b26a-43dd-9111-dc9d425302b6'	System	21 Oct 2020 15:34:58
User entered '21 Oct 2020 11:34'	System	21 Oct 2020 15:34:58

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:12'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 13:42'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:24:47', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3'	System	21 Oct 2020 21:25:07
User entered 'None (1)'	System	21 Oct 2020 21:25:07

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:24:54', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3'	System	21 Oct 2020 21:25:07
User entered 'No (N)'	System	21 Oct 2020 21:25:07

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:24:17', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3'	System	21 Oct 2020 21:25:07
User entered 'No (N)'	System	21 Oct 2020 21:25:07

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:24:22', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3'	System	21 Oct 2020 21:25:07
User entered 'None (1)'	System	21 Oct 2020 21:25:07

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:25:02', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a6bf3acd-6968-4e52-8efd-8b5298f37ac3'	System	21 Oct 2020 21:25:07
User entered '21 Oct 2020 17:25'	System	21 Oct 2020 21:25:07

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 14:37'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 2'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:37', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96'	System	22 Oct 2020 21:43:02
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 21:43:02

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:42', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96'	System	22 Oct 2020 21:43:02
User entered 'No (N)'	System	22 Oct 2020 21:43:02

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:46', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96'	System	22 Oct 2020 21:43:02
User entered 'No (N)'	System	22 Oct 2020 21:43:02

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:52', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96'	System	22 Oct 2020 21:43:02
User entered 'None (1)'	System	22 Oct 2020 21:43:02

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:42:58', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'ace0cb22-b90c-443c-906a-8a90d6e34c96'	System	22 Oct 2020 21:43:02
User entered '22 Oct 2020 17:42'	System	22 Oct 2020 21:43:02

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 3'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered 'None (1)'	System	24 Oct 2020 15:25:44

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:35', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered 'No (N)'	System	24 Oct 2020 15:25:44

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:38', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered 'No (N)'	System	24 Oct 2020 15:25:44

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:42', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered 'None (1)'	System	24 Oct 2020 15:25:44
	System	24 Oct 2020 15:25:44

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:46:59', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'bac12a2e-b26d-4fd6-936f-9f15f5f0841f' User entered '24 Oct 2020 10:46'	System	24 Oct 2020 15:25:44

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 4'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:02', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a'	System	24 Oct 2020 23:25:23
User entered 'None (1)'	System	24 Oct 2020 23:25:23

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:07', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a'	System	24 Oct 2020 23:25:23
User entered 'No (N)'	System	24 Oct 2020 23:25:23

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:11', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a'	System	24 Oct 2020 23:25:23
User entered 'No (N)'	System	24 Oct 2020 23:25:23

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:15', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a' User entered 'None (1)'	System	24 Oct 2020 23:25:23
	System	24 Oct 2020 23:25:23

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:20', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'c60775ba-1dc4-4308-8035-9db649e5666a'	System	24 Oct 2020 23:25:23
User entered '24 Oct 2020 19:25'	System	24 Oct 2020 23:25:23

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 5'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc'	System	25 Oct 2020 22:58:31
User entered 'None (1)'	System	25 Oct 2020 22:58:31

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:17', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc'	System	25 Oct 2020 22:58:31
User entered 'No (N)'	System	25 Oct 2020 22:58:31

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:21', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc'	System	25 Oct 2020 22:58:31
User entered 'No (N)'	System	25 Oct 2020 22:58:31

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc'	System	25 Oct 2020 22:58:31
User entered 'None (1)'	System	25 Oct 2020 22:58:31

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'd9ee6b58-2aac-4ee5-872d-1f41741e5fcc' User entered '25 Oct 2020 18:58'	System	25 Oct 2020 22:58:31
	System	25 Oct 2020 22:58:31

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 6'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2'	System	26 Oct 2020 23:08:55
User entered 'None (1)'	System	26 Oct 2020 23:08:55

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:38', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2'	System	26 Oct 2020 23:08:55
User entered 'No (N)'	System	26 Oct 2020 23:08:55

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:41', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2'	System	26 Oct 2020 23:08:55
User entered 'No (N)'	System	26 Oct 2020 23:08:55

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:46', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2'	System	26 Oct 2020 23:08:55
User entered 'None (1)'	System	26 Oct 2020 23:08:55

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:08:53', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e3e56f40-84d4-470f-820d-1e713a0d63b2'	System	26 Oct 2020 23:08:55
User entered '26 Oct 2020 19:08'	System	26 Oct 2020 23:08:55

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 7'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:01', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17'	System	27 Oct 2020 23:01:16
User entered 'None (1)'	System	27 Oct 2020 23:01:16

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:04', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17'	System	27 Oct 2020 23:01:16
User entered 'No (N)'	System	27 Oct 2020 23:01:16

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:07', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17'	System	27 Oct 2020 23:01:16
User entered 'No (N)'	System	27 Oct 2020 23:01:16

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17'	System	27 Oct 2020 23:01:16
User entered 'None (1)'	System	27 Oct 2020 23:01:16

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'a48d1733-264d-478d-9409-5160d3c37b17'	System	27 Oct 2020 23:01:16
User entered '27 Oct 2020 19:01'	System	27 Oct 2020 23:01:16

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:02', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:06', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:15', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:19', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'None (0)'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:26', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered 'No (N)'	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T11:35:32', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '959ab6a2-5826-47a7-9058-e0322206047f' User entered '21 Oct 2020 11:35'	System	21 Oct 2020 15:35:35
	System	21 Oct 2020 15:35:35

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:12'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 13:42'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:25:47', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:26:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d' User entered 'None (0)'	System	21 Oct 2020 21:28:48
	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:26:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'Some interference with activity (2)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:26:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'Some interference with activity (2)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:26:27', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'None (0)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:28:31', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'Some interference with activity not requiring medical attention (2)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:28:12', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered 'No (N)'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-21T17:28:44', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '941e645e-18a6-40dd-adb0-b6eb0d3ed77d'	System	21 Oct 2020 21:28:48
User entered '21 Oct 2020 17:28'	System	21 Oct 2020 21:28:48

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 14:37'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 2'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered 'None (0)'	System	22 Oct 2020 21:44:13
	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:22', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered 'None (0)'	System	22 Oct 2020 21:44:13
	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:32', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec'	System	22 Oct 2020 21:44:13
User entered 'No interference with activity (1)'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec'	System	22 Oct 2020 21:44:13
User entered 'No interference with activity (1)'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:42', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered 'None (0)'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:43:55', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec'	System	22 Oct 2020 21:44:13
User entered 'No interference with activity (1)'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:44:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec'	System	22 Oct 2020 21:44:13
User entered 'No (N)'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-22T17:44:11', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: 'e5de7e5f-350d-4e21-a7d9-d9814a6288ec' User entered '22 Oct 2020 17:44'	System	22 Oct 2020 21:44:13

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 3'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813'	System	24 Oct 2020 15:26:10
User entered 'None (0)'	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:09', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813'	System	24 Oct 2020 15:26:10
User entered 'None (0)'	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:11', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813'	System	24 Oct 2020 15:26:10
User entered 'None (0)'	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:14', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813'	System	24 Oct 2020 15:26:10
User entered 'None (0)'	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:16', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813'	System	24 Oct 2020 15:26:10
User entered 'None (0)'	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813'	System	24 Oct 2020 15:26:10
User entered 'None (0)'	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:22', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813'	System	24 Oct 2020 15:26:10
User entered 'No (N)'	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T10:47:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '2cea58dd-6853-4b96-85d4-924b7c3c0813'	System	24 Oct 2020 15:26:10
User entered '24 Oct 2020 10:47'	System	24 Oct 2020 15:26:10

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 4'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:25', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19'	System	24 Oct 2020 23:25:53
User entered 'None (0)'	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19'	System	24 Oct 2020 23:25:53
User entered 'None (0)'	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:31', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'None (0)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered 'None (0)'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:37', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19'	System	24 Oct 2020 23:25:53
User entered 'None (0)'	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19'	System	24 Oct 2020 23:25:53
User entered 'None (0)'	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:44', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19'	System	24 Oct 2020 23:25:53
User entered 'No (N)'	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-24T19:25:50', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '278be0c4-c14e-4058-a5e9-616fd23f3e19' User entered '24 Oct 2020 19:25'	System	24 Oct 2020 23:25:53
	System	24 Oct 2020 23:25:53

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 5'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:34', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f'	System	25 Oct 2020 22:58:55
User entered 'None (0)'	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:36', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f'	System	25 Oct 2020 22:58:55
User entered 'None (0)'	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f'	System	25 Oct 2020 22:58:55
User entered 'None (0)'	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:41', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f'	System	25 Oct 2020 22:58:55
User entered 'None (0)'	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:43', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f'	System	25 Oct 2020 22:58:55
User entered 'None (0)'	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:45', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f'	System	25 Oct 2020 22:58:55
User entered 'None (0)'	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:49', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f'	System	25 Oct 2020 22:58:55
User entered 'No (N)'	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-25T18:58:54', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '552fcc14-6aa6-44e1-95b0-6c1bcd28f4f' User entered '25 Oct 2020 18:58'	System	25 Oct 2020 22:58:55
	System	25 Oct 2020 22:58:55

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 6'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:05', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:08', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:10', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:13', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:17', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:19', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1' User entered 'None (0)'	System	26 Oct 2020 23:09:33
	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:24', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1'	System	26 Oct 2020 23:09:33
User entered 'No (N)'	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-26T19:09:29', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '6a26d533-13fa-40c9-8f5a-a8bf0bc062b1'	System	26 Oct 2020 23:09:33
User entered '26 Oct 2020 19:09'	System	26 Oct 2020 23:09:33

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Oct 2020 15:00:28
User entered 'Day 7'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:18', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:20', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:23', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:26', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:28', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:31', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'None (0)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:35', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered 'No (N)'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA62C958-050D-4D5F-89FB-9BDEAA503AD6)', Time: '2020-10-27T19:01:39', User OID: 'PatientReportedOutcome (US3622282)', ODM File OID: '7742640a-5f3f-42f1-9c02-eb3583a81f32'	System	27 Oct 2020 23:01:41
User entered '27 Oct 2020 19:01'	System	27 Oct 2020 23:01:41

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 15:00:28

US3622282

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:08:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 15:00:28

US3622282

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Oct 2020 16:13:51
	(b) (4)	

US3622282

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered '28 Oct 2020'	Junlin Long (b) (4)	28 Oct 2020 16:13:51
	(b) (4)	

US3622282

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	28 Oct 2020 16:13:51
	(b) (4)	

US3622282

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	28 Oct 2020 16:13:51
	(b) (4)	

US3622282

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	28 Oct 2020 16:13:54
	(b) (4)	

US3622282

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 16:13:54

US3622282

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Nov 2020 16:38:33
	(b) (4)	

US3622282

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered '4 Nov 2020'	Junlin Long (b) (4)	04 Nov 2020 16:38:33
	(b) (4)	

US3622282

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	04 Nov 2020 16:38:33
	(b) (4)	

US3622282

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	04 Nov 2020 16:38:33
	(b) (4)	

US3622282

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:52:09
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Nov 2020 16:38:37
	(b) (4)	

US3622282

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 16:38:37

US3622282

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Nov 2020 17:13:09
	(b) (4)	

US3622282

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
	(b) (4)	
User entered '12 Nov 2020'	Junlin Long (b) (4)	12 Nov 2020 17:13:09
	(b) (4)	

US3622282

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Junlin Long (b) (4)	12 Nov 2020 17:13:09
	(b) (4)	

US3622282

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:08:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
	(b) (4)	
User entered 'unable to contact; messages left'	Junlin Long (b) (4)	12 Nov 2020 17:13:09
	(b) (4)	

US3622282

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	14 Nov 2020 19:18:24
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	12 Nov 2020 17:13:12
	(b) (4)	

US3622282

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:08:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:13:12

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:19:05

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:19:05

US3622282

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:08:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:19:05
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:19:05

US3622282

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:08:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:20:33

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[AEID](#)

Audit	User	Time (GMT)
User entered 'USA-US085-2020-mRNA-1273-P301000002'	System	19 Nov 2020 18:57:40
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 18:57:40

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:45:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Foot operation, LLT: Foot surgery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:14:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:14:06
Data point term sent to Coder	System	24 Nov 2020 18:43:57
Query 'For coding purposes, FOOT/ANKLE SURGERY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:43:55
User opened query 'For coding purposes, FOOT/ANKLE SURGERY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	Coder Import (b) (4) (b) (4)	22 Nov 2020 22:24:00
Query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	22 Nov 2020 21:42:01
User opened query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms.' (Site from System).	Coder Import (b) (4) (b) (4)	18 Nov 2020 23:58:52
Data point term sent to Coder	System	18 Nov 2020 17:29:28
User entered 'Foot/Ankle Surgery'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 17:30:01
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	18 Nov 2020 17:30:01
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 17:29:08
User entered '00:00'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:30:01
User entered '05 Nov 2020 00:00'	System	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 19:45:20
	(b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). User entered '1'	System	18 Nov 2020 17:29:08
	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:46:06
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	18 Nov 2020 17:29:08
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[None](#)

Audit	User	Time (GMT)
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Nov 2020 17:29:08
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:45:03
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:46:14
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:45:57
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:45:35
User entered 'participant missed her visit 2 appointment today. Attempted to contact multiple times today. Called emergency contact and he stated she was in the hospital for about 1.5 weeks due to foot/ankle surgery. Contact person with limited knowledge of events.'	(b) (4), (b) (6)	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 17:29:08

US3622282

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:08:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 17:29:08

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:08:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:17:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE, PRODUCTSYNONYM: TRIUMEQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:21:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:21:44
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:20:22
User entered 'triumeq'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'hiv'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '1'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'tablet (TABLET)'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'once daily (QD)'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2010'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:19:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:19:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:19:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:19:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: INDOLE DERIVATIVES, PRODUCT: LURASIDONE HYDROCHLORIDE, PRODUCTSYNONYM: LATUDA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:22:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:22:32
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:21:23
User entered 'latuda'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'bipolar disorder'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '40'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'once daily (QD)'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2020'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:20:37
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:20:37

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DEPAKOTE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 07:16:24
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 07:16:24
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:21:23
User entered 'depakote'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'anxiety'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '500'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'twice daily (BID)'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2000'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:21:13
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:21:13

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:23:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:23:19
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:22:27
User entered 'seroquel'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'paranoia'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '400'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'once daily (QD)'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2000'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:21:55
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:21:55

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:24:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:24:37
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:23:28
User entered 'montelukast'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'asthma'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '10'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'once daily (QD)'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2000'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:22:41
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:22:41

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:25:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 17:25:44
Data point term sent to Coder	System	21 Oct 2020 17:24:31
User entered 'ibuprofen'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'right ankle pain'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '800'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'as needed (PRN)'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '3 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:23:43
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:23:43

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:25:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:25:45
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:24:31
User entered 'lyrica'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'nerve damage'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '150'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'once daily (QD)'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2010'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:24:28
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:24:28

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:26:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:26:36
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:25:34
User entered 'xarelto'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'prophylaxis for Deep vein thrombosis'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '10'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'once daily (QD)'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2017'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:25:24
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 17:25:24

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:27:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:27:41
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:26:37
User entered 'albuterol'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'asthma'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '90'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'ug (ug)'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'other (OTHER)'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'every 4 to 6 hours as needed'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2015'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:26:26
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:26:26

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 21:17:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 21:17:45
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:28:39
User entered 'duoneb (Ipratropium bromide/albuterol)'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'asthma'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0.5/0.3'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'other (OTHER)'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'every 8 hours as needed'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un UNK 2015'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:27:52
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:27:52

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:29:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 17:29:34
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 17:28:43
User entered 'tylenol'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'right ankle pain'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '500'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'mg (mg)'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'as needed (PRN)'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Oral (ORAL)'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'un Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:28:33
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:28:33

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE, PRODUCTSYNONYM: NEOSPORIN [BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:09:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:09:08
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	10 Nov 2020 16:52:09
Data point term sent to Coder	System	05 Nov 2020 18:04:36
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	05 Nov 2020 18:04:15
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'ingredient names updated' (Site from System).	Junlin Long (b) (4) (b) (4)	05 Nov 2020 18:04:15
Signature has been broken.	Junlin Long (b) (4) (b) (4)	05 Nov 2020 18:03:47
User entered 'NEOSPORIN (bacitracin, neomycin and polymyxin B)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	05 Nov 2020 18:03:47
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	26 Oct 2020 14:30:22
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	24 Oct 2020 15:19:20
Data point term sent to Coder	System	21 Oct 2020 17:30:45
User entered 'neosporin'	Junlin Long (b) (4) (b) (4)	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'right ankle pain'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '1'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Other (OTHER)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'application'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'as needed (PRN)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Topical (TOPICAL)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

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

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '3 Oct 2020'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered '0'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 15:19:20
	(b) (4)	
User entered 'No (N)'	Junlin Long (b) (4)	21 Oct 2020 17:30:05
	(b) (4)	

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:30:05

US3622282

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:08:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 17:30:05

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'USA-US085-2020-MRNA-1273-P301000002'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'No (N)'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Susanne'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Doblecki-Lewis'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '1120 NW 14th Street'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'Miami'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered 'FL'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:59:07
User entered '33136'	System	19 Nov 2020 18:57:40

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 11:08:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '19/Nov/2020 18:59'	System	19 Nov 2020 18:59:14

US3622282

Folder: SAE USA-US085-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:08:55

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 entered '1'	(b) (4), (b) (6)	19 Nov 2020 18:59:14