

US3812267 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:55:38

All time stamps listed in this document are displayed in GMT

US3812267

Form: Participant Creation

Generated On: 26 Nov 2020 09:55:38

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
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

Generated On: 26 Nov 2020 09:55:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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

Generated On: 26 Nov 2020 09:55:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:55:38

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

Condition	INTRAUTERINE DEVICE
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

Condition	PAST CIGARETTE USE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:14 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:14
Height (<i>xxx.x</i>)	68 in
Weight (<i>xxx.x</i>)	193 lb
BMI (<i>xxx.x</i>)	29.40691 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	99 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

Date of assessment (*dd MMM yyyy*) 26 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	26 AUG 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

(b) (6)

CLINICAL
MANAGER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108607

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

Generated On: 26 Nov 2020 09:55:38

Height	
Weight	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Height	
Weight	
Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	09:14 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:14
Temperature (xxx.x)	98.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Height	
Weight	
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:41
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	110 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 10:08 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 10:08

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

Generated On: 26 Nov 2020 09:55:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	26 AUG 2020
Collection time (<i>00:00-23:59</i>)	09:58 (24 HR)
Collection date and time (derived)	26 AUG 2020 09:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:38

Collection date (<i>dd MMM yyyy</i>)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:59	26 AUG 2020 09:59
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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 09:55:38

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

26 AUG 2020 10:46

PC Open Date & Time

26 AUG 2020 10:28

PC Close Date & Time

26 AUG 2020 12:58

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	27 AUG 2020 05:45
PC Open Date & Time	26 AUG 2020 13:53
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:38

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 06:16

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 10:04

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:38

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 07:40

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:38

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

98.3 °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

31 AUG 2020 07:12

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 06:56

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 07:01

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

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

26 AUG 2020 10:46

PC Open Date & Time

26 AUG 2020 10:28

PC Close Date & Time

26 AUG 2020 12:58

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

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

27 AUG 2020 05:45

PC Open Date & Time

26 AUG 2020 13:53

PC Close Date & Time

27 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

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

28 AUG 2020 06:13

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

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

29 AUG 2020 10:02

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

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

30 AUG 2020 07:40

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

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

31 AUG 2020 07:12

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

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

01 SEP 2020 06:56

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

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

02 SEP 2020 07:00

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 10:46
PC Open Date & Time	26 AUG 2020 10:28
PC Close Date & Time	26 AUG 2020 12:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 05:45
PC Open Date & Time	26 AUG 2020 13:53
PC Close Date & Time	27 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

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 ☒

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

Yes ☐	
PC Time stamp	28 AUG 2020 06:13
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

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 ☒

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

Yes ☐	
PC Time stamp	29 AUG 2020 10:02
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

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 ☒

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

Yes ☐	
PC Time stamp	30 AUG 2020 07:40
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

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 ☒

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

Yes ☐	
PC Time stamp	31 AUG 2020 07:12
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

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 ☒

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

Yes ☐	
PC Time stamp	01 SEP 2020 06:56
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

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 ☒

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

Yes ☐	
PC Time stamp	02 SEP 2020 07:00
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3812267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812267

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812267

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812267

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	09:17 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:17
Temperature (xxx.x)	96.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

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.

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	21 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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? _____

US3812267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

21 SEP 2020

Collection time (*00:00-23:59*)

09:30 (24 HR)

Collection date and time (derived)

21 SEP 2020 09:30

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:38

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	21 SEP 2020 09:35
Nasopharyngeal Swab 2	No		

US3812267

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

INADVERTENT ERROR SITE DID
NOT CONTACT FOR SCD38

If Contact Not Made, please provide Comments

US3812267

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812267

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812267

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:39 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 08:39
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812267

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

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.

US3812267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	19 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:00 (24 HR)
Collection date and time (derived)	19 OCT 2020 09:00

US3812267

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 09:21:31

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 07:15:29

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 15:50:45
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 07:44:38
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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°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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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01 FEB 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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08 FEB 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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15 FEB 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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22 FEB 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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01 MAR 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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08 MAR 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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17 MAY 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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31 MAY 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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°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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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14 JUN 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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05 JUL 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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12 JUL 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

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19 JUL 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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°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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 AUG 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 SEP 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 SEP 2022 00:01

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20 SEP 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 SEP 2022 00:01

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27 SEP 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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 ☐

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3812267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812267

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812267

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812267

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812267

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:38

Date of Contact	26 AUG 2020
Time of Contact	09:07
Date and Time of Contact (derived)	26 AUG 2020 09:07
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 ☒

US3812267

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:55:38

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3812267

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:55:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

AEID	
Adverse event	WORSENING ANXIETY
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)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	05 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

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

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:55:38

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

Yes ☒

No ☐

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

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

Name of Medication	MIRENA IUD
Prophylaxis	Yes ☐ No ☒
Indication	BIRTH CONTROL
Dose per administration	52
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	EVERY 5 YEARS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	INTRAUTERINE	
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

Name of Medication	ALPRAZOLAM
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	.25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

	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)		01 MAR 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
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	☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	DOSE
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 ☐ Intramuscular ☒

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

	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)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		02 OCT 2020
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 ☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

Name of Medication	ALPRAZOLAM
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING ANXIETY/ANXIETY
Dose per administration	0.25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

	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)	27 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

Name of Medication	LORAZEPAM
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING ANXIETY
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 ☐ Intramuscular ☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

	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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 28 OCT 2020		
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	☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

Name of Medication	LORAZEPAM
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING ANXIETY
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 ☐ Intramuscular ☐

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

	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)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
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 ☐

US3812267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:55:38

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

Visit	Screening	☐
	Visit 1 Day 1	☐
	Visit 2 Day 29	☒
	Visit 3 Day 57	☐
	Visit 4 Day 209	☐
	Visit 5 Day 394	☐
	Visit 6 Day 759	☐

Case Report Form

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	True
Dosing Discontinuation	False
End of Study / Study Discontinuation	False

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

All	False
Date of missed or out of window visit or assessment	29 AUG 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	True
Other, specify	MISSED SAFETY CALL
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3812267

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:55:38

Date of dosing discontinuation (dd MMM yyyy)

26 AUG 2020

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

US3812267

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:55:38

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3812267 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812267

Form: Participant Creation

Generated On: 26 Nov 2020 09:55:38

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3812267'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 14:40:47

US3812267

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:07

US3812267

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 14:40:48

US3812267

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:07

US3812267

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	26 Aug 2020 15:40:07

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 14:40:49

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Age](#)

Audit	User	Time (GMT)
User entered '29'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '29'	System	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Breanna Galibert (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

White

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:55:38

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:43

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '2020'	System	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:19

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 14:40:48

US3812267

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:55:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 15:40:23

US3812267

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:40:23

US3812267

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:55:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:13

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 18:28:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Aug 2020 18:28:45
Data point term sent to Coder	System	29 Aug 2020 18:27:28
User entered 'ANXIETY'	Karen Knapp (b) (4)	29 Aug 2020 18:17:30
	(b) (4)	

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:17:30

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please expand the abbreviation. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:25:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Intrauterine contraception, LLT: Intra-uterine contraceptive device - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:06:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 17:06:21
Data point term sent to Coder	System	26 Oct 2020 16:58:48
Query 'Per MM, please expand the abbreviation. ' answered with 'Updated. Thank you ' (Site from DM).	Lyly Dang (b) (4)	26 Oct 2020 16:58:21
Coding entries removed.	Lyly Dang (b) (4)	26 Oct 2020 16:58:02
User entered 'intrauterine device' reason for change: Data Entry Error	Lyly Dang (b) (4)	26 Oct 2020 16:58:02
User opened query 'Per MM, please expand the abbreviation. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:58:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Intrauterine contraception, LLT: Intra-uterine contraceptive device - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 18:28:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Aug 2020 18:28:51
Data point term sent to Coder	System	29 Aug 2020 18:27:30
User entered 'IUD'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '2017'	System	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:17:42

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Ex-tobacco user, LLT: Ex-smoker - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:51:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 05:51:40
Data point term sent to Coder	System	30 Sep 2020 20:27:08
User entered 'PAST CIGARETTE USE'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 2011'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '2009'	System	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '2011'	System	30 Sep 2020 20:26:36

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '09:14'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 09:14'	System	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '68' in	Karen Knapp (b) (4)	29 Aug 2020 18:19:01
DataPoint set to visible.	(b) (4) System	26 Aug 2020 15:40:23

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '193' lb	Karen Knapp (b) (4)	29 Aug 2020 18:19:01
DataPoint set to visible.	(b) (4) System	26 Aug 2020 15:40:23

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '29.40691'	System	29 Aug 2020 18:19:01
DataPoint set to visible.	System	26 Aug 2020 15:40:23

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	29 Aug 2020 18:19:01
DataPoint set to visible.	System	26 Aug 2020 15:40:23

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.9' F	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '99'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '17'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '140'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '75'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:19:01

US3812267

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:11

US3812267

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:11

US3812267

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:42

US3812267

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:42

US3812267

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:42

US3812267

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:42

US3812267

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:42

US3812267

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:42

US3812267

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:42

US3812267

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:55:38

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:19:42

US3812267

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:20:27

US3812267

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:20:27

US3812267

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:20:27

US3812267

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Result](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 12:24:58
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	04 Sep 2020 12:24:58
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Aug 2020 18:20:27
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 18:20:27
	(b) (4)	

US3812267

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 06:13:38
Query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	15 Oct 2020 23:44:19
User opened query 'Per CDM: If FSH sample was not collected, Collection Date and Collection Time should be blank.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:20:56
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:20:27

US3812267

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Collection date](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	15 Oct 2020 23:44:15
User entered '26 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	04 Sep 2020 12:24:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:20:27

US3812267

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Collection time](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	15 Oct 2020 23:44:15
User entered '09:26' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	04 Sep 2020 12:24:58
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 18:20:27

US3812267

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 23:44:15
User entered '26 Aug 2020 09:26'	System	04 Sep 2020 12:24:58
User entered empty.	System	29 Aug 2020 18:20:27

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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 entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

[Specify](#)

Audit			User	Time (GMT)
User entered	(b) (6)	CLINICAL	Karen Knapp (b) (4)	29 Aug 2020 18:21:06
MANAGER'			(b) (4)	

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:55:38

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:06

US3812267

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:03

US3812267

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:03

US3812267

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:03

US3812267

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	26 Aug 2020 15:41:03

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 14:54:43

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '108607'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 14:54:43

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 14:54:43

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:29

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:29

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:29

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:29

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:21:29

US3812267

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4)	21 Sep 2020 19:13:44
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 09:46:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:01:26

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:38

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:51:48
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' answered with 'data removed' (Site from DM).	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:22:13
User entered empty; reason for change Per Query Resolution	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:22:06
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:36:24
User entered '68' in	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:38

Weight

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Karen Knapp (b) (4)	01 Nov 2020 21:21:52
User entered '193' lb	Karen Knapp (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:38

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:51:48
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' answered with 'data removed' (Site from DM).	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:22:13
User entered empty; reason for change Per Query Resolution	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:22:06
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:36:24
User entered '68' in	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:38

Weight

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Karen Knapp (b) (4)	01 Nov 2020 21:21:52
User entered '193' lb	Karen Knapp (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '09:14'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 09:14'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.9' F	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '99'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '17'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '80'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:38

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:51:48
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' answered with 'data removed' (Site from DM).	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:22:13
User entered empty; reason for change Per Query Resolution	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:22:06
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:36:24
User entered '68' in	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:55:38

Weight

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Karen Knapp (b) (4)	01 Nov 2020 21:21:52
User entered '193' lb	Karen Knapp (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '10:41'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 10:41'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Pulse (xxx)

Audit	User	Time (GMT)
User entered '110'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '14'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '144'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '92'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Aug 2020 18:23:38

US3812267

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	17 Sep 2020 00:16:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Aug 2020 18:23:47

US3812267

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	17 Sep 2020 00:16:51
User entered '26 Aug 2020'	Karen Knapp (b) (4)	29 Aug 2020 18:23:47

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test form at Screening and Visit 1 Day 1. Please consider updating "Was the pregnancy test performed?" and "Was FSH sample collected?"to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:58:41
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test form at Screening and Visit 1 Day 1. Please consider updating "Was the pregnancy test performed?" and "Was FSH sample collected?"to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	29 Oct 2020 17:47:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	29 Oct 2020 17:47:27
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test form at Screening and Visit 1 Day 1. Please consider updating "Was the pregnancy test performed?" and "Was FSH sample collected?"to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:42:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	26 Oct 2020 17:00:11
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:04:29

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' answered with 'UPDATED PER QUERY ' (Site from DM).	Breanna Galibert (b) (4)	06 Oct 2020 21:02:51
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:02:48
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:12:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Aug 2020 18:24:06

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	29 Oct 2020 17:47:27
User entered '26 Aug 2020' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	26 Oct 2020 17:00:11
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	06 Oct 2020 21:02:48
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:06

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	29 Oct 2020 17:47:27
User entered 'Urine (URINE)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	26 Oct 2020 17:00:11
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4) (b) (4)	06 Oct 2020 21:02:48
User entered 'Urine (URINE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:06

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	29 Oct 2020 17:47:27
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	26 Oct 2020 17:00:11
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 21:02:48
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Aug 2020 18:24:06
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:06

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:42:54
Query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you.' answered with 'EDC entered' (Site from DM).	Lyly Dang (b) (4)	26 Oct 2020 17:01:36
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	26 Oct 2020 17:00:11
User opened query 'Per CDM: Data is required. Please select "No" as per above query raised. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:51:58
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	06 Oct 2020 21:02:48
User entered 'No (N)'	Karen Knapp (b) (4)	29 Aug 2020 18:24:06

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:06

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:06

US3812267

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:24:06

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '10:08'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 10:08'	System	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4) (b) (4)	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 15:41:23

US3812267

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:24

US3812267

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:24

US3812267

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:58'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:24

US3812267

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 09:58'	System	29 Aug 2020 18:24:24

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:59'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 09:59'	System	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 18:24:44

US3812267

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:24:50

US3812267

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 18:24:50

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:02', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2c76c734-67b6-4d30-b40b-c994506174a0'	System	26 Aug 2020 15:46:16
User entered 'Yes (Y)'	System	26 Aug 2020 15:46:16

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:06', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2c76c734-67b6-4d30-b40b-c994506174a0'	System	26 Aug 2020 15:46:16
User entered '98.8'	System	26 Aug 2020 15:46:16

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:10', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2c76c734-67b6-4d30-b40b-c994506174a0'	System	26 Aug 2020 15:46:16
User entered 'No (N)'	System	26 Aug 2020 15:46:16

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:14', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2c76c734-67b6-4d30-b40b-c994506174a0'	System	26 Aug 2020 15:46:16
User entered '26 Aug 2020 10:46'	System	26 Aug 2020 15:46:16

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 10:28'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:58'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:45', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2cdfc156-4046-4b04-a466-ff49d5aa5cb3' User entered 'Yes (Y)'	System	27 Aug 2020 10:45:59
	System	27 Aug 2020 10:45:59

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:51', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2cdfc156-4046-4b04-a466-ff49d5aa5cb3' User entered '98.3'	System	27 Aug 2020 10:45:59
	System	27 Aug 2020 10:45:59

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:53', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2cdfc156-4046-4b04-a466-ff49d5aa5cb3'	System	27 Aug 2020 10:45:59
User entered 'No (N)'	System	27 Aug 2020 10:45:59

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:56', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2cdfc156-4046-4b04-a466-ff49d5aa5cb3'	System	27 Aug 2020 10:45:59
User entered '27 Aug 2020 05:45'	System	27 Aug 2020 10:45:59

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 13:53'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 2'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:14:02', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2da09917-fce4-4095-acf8-b681cae4cda8'	System	28 Aug 2020 11:16:09
User entered 'Yes (Y)'	System	28 Aug 2020 11:16:09

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:16:03', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2da09917-fce4-4095-acf8-b681cae4cda8'	System	28 Aug 2020 11:16:09
User entered '97.9'	System	28 Aug 2020 11:16:09

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:16:05', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2da09917-fce4-4095-acf8-b681cae4cda8'	System	28 Aug 2020 11:16:09
User entered 'No (N)'	System	28 Aug 2020 11:16:09

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:16:07', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2da09917-fce4-4095-acf8-b681cae4cda8'	System	28 Aug 2020 11:16:09
User entered '28 Aug 2020 06:16'	System	28 Aug 2020 11:16:09

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 3'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:39', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '9f9ee263-fcb6-4851-a32f-ee721c9b5825'	System	29 Aug 2020 15:04:32
User entered 'Yes (Y)'	System	29 Aug 2020 15:04:32

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:04:23', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '9f9ee263-fcb6-4851-a32f-ee721c9b5825'	System	29 Aug 2020 15:04:32
User entered '98.1'	System	29 Aug 2020 15:04:32

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:04:26', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '9f9ee263-fcb6-4851-a32f-ee721c9b5825'	System	29 Aug 2020 15:04:32
User entered 'No (N)'	System	29 Aug 2020 15:04:32

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:04:29', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '9f9ee263-fcb6-4851-a32f-ee721c9b5825'	System	29 Aug 2020 15:04:32
User entered '29 Aug 2020 10:04'	System	29 Aug 2020 15:04:32

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 4'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:00', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '9a51e174-d1eb-4b58-9057-c5a1c810b40f'	System	30 Aug 2020 12:40:13
User entered 'Yes (Y)'	System	30 Aug 2020 12:40:13

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:06', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '9a51e174-d1eb-4b58-9057-c5a1c810b40f' User entered '98.4'	System	30 Aug 2020 12:40:13

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:08', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '9a51e174-d1eb-4b58-9057-c5a1c810b40f'	System	30 Aug 2020 12:40:13
User entered 'No (N)'	System	30 Aug 2020 12:40:13

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:11', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '9a51e174-d1eb-4b58-9057-c5a1c810b40f' User entered '30 Aug 2020 07:40'	System	30 Aug 2020 12:40:13
	System	30 Aug 2020 12:40:13

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 5'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:12', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b36ab296-6381-49aa-bc4b-613f7a96e9e0'	System	31 Aug 2020 12:12:23
User entered 'Yes (Y)'	System	31 Aug 2020 12:12:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:15', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b36ab296-6381-49aa-bc4b-613f7a96e9e0'	System	31 Aug 2020 12:12:23
User entered '98.3'	System	31 Aug 2020 12:12:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:18', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b36ab296-6381-49aa-bc4b-613f7a96e9e0'	System	31 Aug 2020 12:12:23
User entered 'No (N)'	System	31 Aug 2020 12:12:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:20', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b36ab296-6381-49aa-bc4b-613f7a96e9e0'	System	31 Aug 2020 12:12:23
User entered '31 Aug 2020 07:12'	System	31 Aug 2020 12:12:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 6'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:39', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '40da83b6-f12e-449b-9742-635eba6bd3a4' User entered 'Yes (Y)'	System	01 Sep 2020 11:56:53

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:44', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '40da83b6-f12e-449b-9742-635eba6bd3a4'	System	01 Sep 2020 11:56:53
User entered '98.5'	System	01 Sep 2020 11:56:53

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:47', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '40da83b6-f12e-449b-9742-635eba6bd3a4' User entered 'No (N)'	System	01 Sep 2020 11:56:53

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:49', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '40da83b6-f12e-449b-9742-635eba6bd3a4' User entered '01 Sep 2020 06:56'	System	01 Sep 2020 11:56:53
	System	01 Sep 2020 11:56:53

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 7'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:50', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'eedf3cb8-8648-4d3b-9711-3103c98922c9'	System	02 Sep 2020 12:01:05
User entered 'Yes (Y)'	System	02 Sep 2020 12:01:05

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:56', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'eedf3cb8-8648-4d3b-9711-3103c98922c9'	System	02 Sep 2020 12:01:05
User entered '98.4'	System	02 Sep 2020 12:01:05

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:59', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'eedf3cb8-8648-4d3b-9711-3103c98922c9'	System	02 Sep 2020 12:01:05
User entered 'No (N)'	System	02 Sep 2020 12:01:05

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:01:01', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'eedf3cb8-8648-4d3b-9711-3103c98922c9' User entered '02 Sep 2020 07:01'	System	02 Sep 2020 12:01:05
	System	02 Sep 2020 12:01:05

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:19', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'dcc9a63f-58d5-4cbc-b7d9-7a99af596e60'	System	26 Aug 2020 15:46:40
User entered 'None (1)'	System	26 Aug 2020 15:46:40

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:23', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'dcc9a63f-58d5-4cbc-b7d9-7a99af596e60'	System	26 Aug 2020 15:46:40
User entered 'No (N)'	System	26 Aug 2020 15:46:40

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:28', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'dcc9a63f-58d5-4cbc-b7d9-7a99af596e60'	System	26 Aug 2020 15:46:40
User entered 'No (N)'	System	26 Aug 2020 15:46:40

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:33', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'dcc9a63f-58d5-4cbc-b7d9-7a99af596e60'	System	26 Aug 2020 15:46:40
User entered 'None (1)'	System	26 Aug 2020 15:46:40

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:35', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'dcc9a63f-58d5-4cbc-b7d9-7a99af596e60'	System	26 Aug 2020 15:46:40
User entered '26 Aug 2020 10:46'	System	26 Aug 2020 15:46:40

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 10:28'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:58'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:44:15', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c22991f5-33e3-4f3c-9e68-8090adbc0acd'	System	27 Aug 2020 10:45:05
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 10:45:05

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:44:32', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c22991f5-33e3-4f3c-9e68-8090adbc0acd'	System	27 Aug 2020 10:45:05
User entered 'No (N)'	System	27 Aug 2020 10:45:05

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:44:42', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c22991f5-33e3-4f3c-9e68-8090adbc0acd'	System	27 Aug 2020 10:45:05
User entered 'No (N)'	System	27 Aug 2020 10:45:05

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:44:57', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c22991f5-33e3-4f3c-9e68-8090adbc0acd' User entered 'None (1)'	System	27 Aug 2020 10:45:05
	System	27 Aug 2020 10:45:05

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:03', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c22991f5-33e3-4f3c-9e68-8090adbc0acd' User entered '27 Aug 2020 05:45'	System	27 Aug 2020 10:45:05
	System	27 Aug 2020 10:45:05

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 13:53'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 2'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:10', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2771236c-9b04-47a5-9602-7bdfc03418d7'	System	28 Aug 2020 11:13:33
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 11:13:33

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:13', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2771236c-9b04-47a5-9602-7bdfc03418d7'	System	28 Aug 2020 11:13:33
User entered 'No (N)'	System	28 Aug 2020 11:13:33

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:15', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2771236c-9b04-47a5-9602-7bdfc03418d7'	System	28 Aug 2020 11:13:33
User entered 'No (N)'	System	28 Aug 2020 11:13:33

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:29', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2771236c-9b04-47a5-9602-7bdfc03418d7'	System	28 Aug 2020 11:13:33
User entered 'None (1)'	System	28 Aug 2020 11:13:33

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:32', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '2771236c-9b04-47a5-9602-7bdfc03418d7'	System	28 Aug 2020 11:13:33
User entered '28 Aug 2020 06:13'	System	28 Aug 2020 11:13:33

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 3'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:10', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '65b7ad6f-95af-49ca-8ed3-a4ca813e29b8'	System	29 Aug 2020 15:02:21
User entered 'None (1)'	System	29 Aug 2020 15:02:21

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:13', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '65b7ad6f-95af-49ca-8ed3-a4ca813e29b8'	System	29 Aug 2020 15:02:21
User entered 'No (N)'	System	29 Aug 2020 15:02:21

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:15', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '65b7ad6f-95af-49ca-8ed3-a4ca813e29b8'	System	29 Aug 2020 15:02:21
User entered 'No (N)'	System	29 Aug 2020 15:02:21

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:17', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '65b7ad6f-95af-49ca-8ed3-a4ca813e29b8'	System	29 Aug 2020 15:02:21
User entered 'None (1)'	System	29 Aug 2020 15:02:21

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:19', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '65b7ad6f-95af-49ca-8ed3-a4ca813e29b8'	System	29 Aug 2020 15:02:21
User entered '29 Aug 2020 10:02'	System	29 Aug 2020 15:02:21

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 4'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:13', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'f84348ec-6716-479c-97cf-6226d0621fe1'	System	30 Aug 2020 12:40:23
User entered 'None (1)'	System	30 Aug 2020 12:40:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:16', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'f84348ec-6716-479c-97cf-6226d0621fe1'	System	30 Aug 2020 12:40:23
User entered 'No (N)'	System	30 Aug 2020 12:40:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:18', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'f84348ec-6716-479c-97cf-6226d0621fe1'	System	30 Aug 2020 12:40:23
User entered 'No (N)'	System	30 Aug 2020 12:40:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:19', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'f84348ec-6716-479c-97cf-6226d0621fe1'	System	30 Aug 2020 12:40:23
User entered 'None (1)'	System	30 Aug 2020 12:40:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:21', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'f84348ec-6716-479c-97cf-6226d0621fe1'	System	30 Aug 2020 12:40:23
User entered '30 Aug 2020 07:40'	System	30 Aug 2020 12:40:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 5'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:24', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '0a75b24d-55de-41b3-962a-7c693d535664'	System	31 Aug 2020 12:12:34
User entered 'None (1)'	System	31 Aug 2020 12:12:34

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:26', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '0a75b24d-55de-41b3-962a-7c693d535664'	System	31 Aug 2020 12:12:34
User entered 'No (N)'	System	31 Aug 2020 12:12:34

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:27', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '0a75b24d-55de-41b3-962a-7c693d535664'	System	31 Aug 2020 12:12:34
User entered 'No (N)'	System	31 Aug 2020 12:12:34

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:29', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '0a75b24d-55de-41b3-962a-7c693d535664'	System	31 Aug 2020 12:12:34
User entered 'None (1)'	System	31 Aug 2020 12:12:34

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:33', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '0a75b24d-55de-41b3-962a-7c693d535664'	System	31 Aug 2020 12:12:34
User entered '31 Aug 2020 07:12'	System	31 Aug 2020 12:12:34

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 6'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:26', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '17ad2703-933e-4257-94cc-33b4c2090d24'	System	01 Sep 2020 11:56:36
User entered 'None (1)'	System	01 Sep 2020 11:56:36

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:28', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '17ad2703-933e-4257-94cc-33b4c2090d24'	System	01 Sep 2020 11:56:36
User entered 'No (N)'	System	01 Sep 2020 11:56:36

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:29', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '17ad2703-933e-4257-94cc-33b4c2090d24'	System	01 Sep 2020 11:56:36
User entered 'No (N)'	System	01 Sep 2020 11:56:36

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:31', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '17ad2703-933e-4257-94cc-33b4c2090d24'	System	01 Sep 2020 11:56:36
User entered 'None (1)'	System	01 Sep 2020 11:56:36

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:33', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '17ad2703-933e-4257-94cc-33b4c2090d24'	System	01 Sep 2020 11:56:36
User entered '01 Sep 2020 06:56'	System	01 Sep 2020 11:56:36

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 7'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:39', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a646b0eb-30ba-4e3c-99eb-a8f76fbc94fa'	System	02 Sep 2020 12:00:52
User entered 'None (1)'	System	02 Sep 2020 12:00:52

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:41', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a646b0eb-30ba-4e3c-99eb-a8f76fbc94fa'	System	02 Sep 2020 12:00:52
User entered 'No (N)'	System	02 Sep 2020 12:00:52

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:42', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a646b0eb-30ba-4e3c-99eb-a8f76fbc94fa' User entered 'No (N)'	System	02 Sep 2020 12:00:52

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

[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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:43', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a646b0eb-30ba-4e3c-99eb-a8f76fbc94fa' User entered 'None (1)'	System	02 Sep 2020 12:00:52
	System	02 Sep 2020 12:00:52

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:46', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a646b0eb-30ba-4e3c-99eb-a8f76fbc94fa' User entered '02 Sep 2020 07:00'	System	02 Sep 2020 12:00:52
	System	02 Sep 2020 12:00:52

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:39', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'ffcb446f-e442-404d-9436-3cd005d9a378'	System	26 Aug 2020 15:47:02
User entered 'None (0)'	System	26 Aug 2020 15:47:02

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:42', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'ffcb446f-e442-404d-9436-3cd005d9a378'	System	26 Aug 2020 15:47:02
User entered 'None (0)'	System	26 Aug 2020 15:47:02

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:43', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'ffcb446f-e442-404d-9436-3cd005d9a378'	System	26 Aug 2020 15:47:02
User entered 'None (0)'	System	26 Aug 2020 15:47:02

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:45', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'ffcb446f-e442-404d-9436-3cd005d9a378'	System	26 Aug 2020 15:47:02
User entered 'None (0)'	System	26 Aug 2020 15:47:02

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:47', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'ffcb446f-e442-404d-9436-3cd005d9a378'	System	26 Aug 2020 15:47:02
User entered 'None (0)'	System	26 Aug 2020 15:47:02

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:48', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'ffcb446f-e442-404d-9436-3cd005d9a378'	System	26 Aug 2020 15:47:02
User entered 'None (0)'	System	26 Aug 2020 15:47:02

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:56', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'ffcb446f-e442-404d-9436-3cd005d9a378'	System	26 Aug 2020 15:47:02
User entered 'No (N)'	System	26 Aug 2020 15:47:02

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-26T10:46:58', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'ffcb446f-e442-404d-9436-3cd005d9a378'	System	26 Aug 2020 15:47:02
User entered '26 Aug 2020 10:46'	System	26 Aug 2020 15:47:02

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 10:28'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:58'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:17', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a053e3fb-faa5-4c58-96a7-3179da00f5d2'	System	27 Aug 2020 10:45:39
User entered 'None (0)'	System	27 Aug 2020 10:45:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:20', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a053e3fb-faa5-4c58-96a7-3179da00f5d2'	System	27 Aug 2020 10:45:39
User entered 'None (0)'	System	27 Aug 2020 10:45:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:24', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a053e3fb-faa5-4c58-96a7-3179da00f5d2'	System	27 Aug 2020 10:45:39
User entered 'None (0)'	System	27 Aug 2020 10:45:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:25', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a053e3fb-faa5-4c58-96a7-3179da00f5d2'	System	27 Aug 2020 10:45:39
User entered 'None (0)'	System	27 Aug 2020 10:45:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:27', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a053e3fb-faa5-4c58-96a7-3179da00f5d2'	System	27 Aug 2020 10:45:39
User entered 'None (0)'	System	27 Aug 2020 10:45:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:29', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a053e3fb-faa5-4c58-96a7-3179da00f5d2'	System	27 Aug 2020 10:45:39
User entered 'None (0)'	System	27 Aug 2020 10:45:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:34', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a053e3fb-faa5-4c58-96a7-3179da00f5d2'	System	27 Aug 2020 10:45:39
User entered 'No (N)'	System	27 Aug 2020 10:45:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-27T05:45:37', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'a053e3fb-faa5-4c58-96a7-3179da00f5d2'	System	27 Aug 2020 10:45:39
User entered '27 Aug 2020 05:45'	System	27 Aug 2020 10:45:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 13:53'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 2'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:36', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b6c9db3e-8246-4b47-b7cf-a8af71a8f814'	System	28 Aug 2020 11:13:58
User entered 'None (0)'	System	28 Aug 2020 11:13:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:39', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b6c9db3e-8246-4b47-b7cf-a8af71a8f814'	System	28 Aug 2020 11:13:58
User entered 'None (0)'	System	28 Aug 2020 11:13:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:43', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b6c9db3e-8246-4b47-b7cf-a8af71a8f814'	System	28 Aug 2020 11:13:58
User entered 'None (0)'	System	28 Aug 2020 11:13:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:46', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b6c9db3e-8246-4b47-b7cf-a8af71a8f814'	System	28 Aug 2020 11:13:58
User entered 'None (0)'	System	28 Aug 2020 11:13:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:48', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b6c9db3e-8246-4b47-b7cf-a8af71a8f814'	System	28 Aug 2020 11:13:58
User entered 'None (0)'	System	28 Aug 2020 11:13:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:50', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b6c9db3e-8246-4b47-b7cf-a8af71a8f814'	System	28 Aug 2020 11:13:58
User entered 'None (0)'	System	28 Aug 2020 11:13:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:53', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b6c9db3e-8246-4b47-b7cf-a8af71a8f814'	System	28 Aug 2020 11:13:58
User entered 'No (N)'	System	28 Aug 2020 11:13:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-28T06:13:56', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'b6c9db3e-8246-4b47-b7cf-a8af71a8f814'	System	28 Aug 2020 11:13:58
User entered '28 Aug 2020 06:13'	System	28 Aug 2020 11:13:58

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 3'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:24', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '89019ac3-448b-4fe4-bb26-c274775c8fee'	System	29 Aug 2020 15:02:37
User entered 'None (0)'	System	29 Aug 2020 15:02:37

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:25', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '89019ac3-448b-4fe4-bb26-c274775c8fee'	System	29 Aug 2020 15:02:37
User entered 'None (0)'	System	29 Aug 2020 15:02:37

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:27', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '89019ac3-448b-4fe4-bb26-c274775c8fee'	System	29 Aug 2020 15:02:37
User entered 'None (0)'	System	29 Aug 2020 15:02:37

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:28', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '89019ac3-448b-4fe4-bb26-c274775c8fee'	System	29 Aug 2020 15:02:37
User entered 'None (0)'	System	29 Aug 2020 15:02:37

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:29', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '89019ac3-448b-4fe4-bb26-c274775c8fee'	System	29 Aug 2020 15:02:37
User entered 'None (0)'	System	29 Aug 2020 15:02:37

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:30', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '89019ac3-448b-4fe4-bb26-c274775c8fee'	System	29 Aug 2020 15:02:37
User entered 'None (0)'	System	29 Aug 2020 15:02:37

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:32', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '89019ac3-448b-4fe4-bb26-c274775c8fee'	System	29 Aug 2020 15:02:37
User entered 'No (N)'	System	29 Aug 2020 15:02:37

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-29T10:02:34', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '89019ac3-448b-4fe4-bb26-c274775c8fee'	System	29 Aug 2020 15:02:37
User entered '29 Aug 2020 10:02'	System	29 Aug 2020 15:02:37

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 4'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:24', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c4fa9d38-2d17-42fd-830c-c01d4f517d99'	System	30 Aug 2020 12:40:39
User entered 'None (0)'	System	30 Aug 2020 12:40:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:25', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c4fa9d38-2d17-42fd-830c-c01d4f517d99'	System	30 Aug 2020 12:40:39
User entered 'None (0)'	System	30 Aug 2020 12:40:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:26', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c4fa9d38-2d17-42fd-830c-c01d4f517d99'	System	30 Aug 2020 12:40:39
User entered 'None (0)'	System	30 Aug 2020 12:40:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:27', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c4fa9d38-2d17-42fd-830c-c01d4f517d99'	System	30 Aug 2020 12:40:39
User entered 'None (0)'	System	30 Aug 2020 12:40:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:28', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c4fa9d38-2d17-42fd-830c-c01d4f517d99'	System	30 Aug 2020 12:40:39
User entered 'None (0)'	System	30 Aug 2020 12:40:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:31', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c4fa9d38-2d17-42fd-830c-c01d4f517d99'	System	30 Aug 2020 12:40:39
User entered 'None (0)'	System	30 Aug 2020 12:40:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:33', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c4fa9d38-2d17-42fd-830c-c01d4f517d99'	System	30 Aug 2020 12:40:39
User entered 'No (N)'	System	30 Aug 2020 12:40:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-30T07:40:35', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'c4fa9d38-2d17-42fd-830c-c01d4f517d99'	System	30 Aug 2020 12:40:39
User entered '30 Aug 2020 07:40'	System	30 Aug 2020 12:40:39

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 5'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:36', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'fd63ff8a-6640-4566-9f8f-cac359097ecd'	System	31 Aug 2020 12:12:54
User entered 'None (0)'	System	31 Aug 2020 12:12:54

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:37', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'fd63ff8a-6640-4566-9f8f-cac359097ecd'	System	31 Aug 2020 12:12:54
User entered 'None (0)'	System	31 Aug 2020 12:12:54

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:39', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'fd63ff8a-6640-4566-9f8f-cac359097ecd'	System	31 Aug 2020 12:12:54
User entered 'None (0)'	System	31 Aug 2020 12:12:54

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:40', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'fd63ff8a-6640-4566-9f8f-cac359097ecd'	System	31 Aug 2020 12:12:54
User entered 'None (0)'	System	31 Aug 2020 12:12:54

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:42', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'fd63ff8a-6640-4566-9f8f-cac359097ecd'	System	31 Aug 2020 12:12:54
User entered 'None (0)'	System	31 Aug 2020 12:12:54

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:43', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'fd63ff8a-6640-4566-9f8f-cac359097ecd'	System	31 Aug 2020 12:12:54
User entered 'None (0)'	System	31 Aug 2020 12:12:54

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:47', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'fd63ff8a-6640-4566-9f8f-cac359097ecd'	System	31 Aug 2020 12:12:54
User entered 'No (N)'	System	31 Aug 2020 12:12:54

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-08-31T07:12:49', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: 'fd63ff8a-6640-4566-9f8f-cac359097ecd'	System	31 Aug 2020 12:12:54
User entered '31 Aug 2020 07:12'	System	31 Aug 2020 12:12:54

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 6'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:11', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '697583ea-4991-4f2c-aac8-d563f31db913'	System	01 Sep 2020 11:56:24
User entered 'None (0)'	System	01 Sep 2020 11:56:24

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:12', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '697583ea-4991-4f2c-aac8-d563f31db913'	System	01 Sep 2020 11:56:24
User entered 'None (0)'	System	01 Sep 2020 11:56:24

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:13', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '697583ea-4991-4f2c-aac8-d563f31db913'	System	01 Sep 2020 11:56:24
User entered 'None (0)'	System	01 Sep 2020 11:56:24

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:15', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '697583ea-4991-4f2c-aac8-d563f31db913'	System	01 Sep 2020 11:56:24
User entered 'None (0)'	System	01 Sep 2020 11:56:24

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:16', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '697583ea-4991-4f2c-aac8-d563f31db913'	System	01 Sep 2020 11:56:24
User entered 'None (0)'	System	01 Sep 2020 11:56:24

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:17', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '697583ea-4991-4f2c-aac8-d563f31db913'	System	01 Sep 2020 11:56:24
User entered 'None (0)'	System	01 Sep 2020 11:56:24

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:20', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '697583ea-4991-4f2c-aac8-d563f31db913'	System	01 Sep 2020 11:56:24
User entered 'No (N)'	System	01 Sep 2020 11:56:24

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-01T06:56:22', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '697583ea-4991-4f2c-aac8-d563f31db913'	System	01 Sep 2020 11:56:24
User entered '01 Sep 2020 06:56'	System	01 Sep 2020 11:56:24

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 7'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:27', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '4d7eddd7-d635-4d63-bdc6-9fd036d25f89'	System	02 Sep 2020 12:00:40
User entered 'None (0)'	System	02 Sep 2020 12:00:40

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:28', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '4d7eddd7-d635-4d63-bdc6-9fd036d25f89'	System	02 Sep 2020 12:00:40
User entered 'None (0)'	System	02 Sep 2020 12:00:40

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:29', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '4d7eddd7-d635-4d63-bdc6-9fd036d25f89'	System	02 Sep 2020 12:00:40
User entered 'None (0)'	System	02 Sep 2020 12:00:40

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:30', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '4d7eddd7-d635-4d63-bdc6-9fd036d25f89'	System	02 Sep 2020 12:00:40
User entered 'None (0)'	System	02 Sep 2020 12:00:40

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:31', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '4d7eddd7-d635-4d63-bdc6-9fd036d25f89'	System	02 Sep 2020 12:00:40
User entered 'None (0)'	System	02 Sep 2020 12:00:40

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:32', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '4d7eddd7-d635-4d63-bdc6-9fd036d25f89'	System	02 Sep 2020 12:00:40
User entered 'None (0)'	System	02 Sep 2020 12:00:40

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

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 (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:34', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '4d7eddd7-d635-4d63-bdc6-9fd036d25f89'	System	02 Sep 2020 12:00:40
User entered 'No (N)'	System	02 Sep 2020 12:00:40

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-09-02T07:00:36', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '4d7eddd7-d635-4d63-bdc6-9fd036d25f89'	System	02 Sep 2020 12:00:40
User entered '02 Sep 2020 07:00'	System	02 Sep 2020 12:00:40

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:41:23

US3812267

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:58:00

US3812267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4)	10 Nov 2020 23:22:13
User entered '2 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:58:00

US3812267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 17:58:00

US3812267

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:58:00

US3812267

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:58:05

US3812267

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:58:05

US3812267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:58:15

US3812267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:58:15

US3812267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 17:58:15

US3812267

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:58:15

US3812267

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:58:40

US3812267

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:58:40

US3812267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	16 Sep 2020 15:35:51

US3812267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Karen Knapp (b) (4) (b) (4)	16 Sep 2020 15:35:51

US3812267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	16 Sep 2020 15:35:51

US3812267

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	16 Sep 2020 15:35:51

US3812267

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	16 Sep 2020 15:35:55

US3812267

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 15:35:55

US3812267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 15:55:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 15:55:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Oct 2020 15:55:29
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 20:28:37
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 20:28:37
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	30 Sep 2020 20:27:23

US3812267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '21 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Oct 2020 15:55:29
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 20:28:37
User entered '21 Sep 2020'	Breanna Galibert (b) (4)	30 Sep 2020 20:27:23

US3812267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

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

Audit	User		Time (GMT)
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	(b) (4)	19 Oct 2020 15:55:29
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	(b) (4)	30 Sep 2020 20:28:37
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	(b) (4)	30 Sep 2020 20:27:23

US3812267

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	19 Oct 2020 15:55:29
User entered empty.	System	30 Sep 2020 20:28:37
User entered 'VISIT2'	System	30 Sep 2020 20:27:23

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '09:17'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 09:17'	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.8' F	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Pulse (xxx)

Audit	User	Time (GMT)
User entered '68'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '16'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '78'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Pulse (xxx)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:56:29

US3812267

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 15:54:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 15:54:52
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Oct 2020 15:54:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 20:28:24
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 20:28:24
User entered 'No (N)'	Breanna Galibert (b) (4)	30 Sep 2020 20:27:36

US3812267

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:27:36

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 15:54:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 15:54:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Oct 2020 15:54:36
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 20:28:16
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 20:28:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	30 Sep 2020 20:27:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

Date of test (dd MMM yyyy)

Audit	User		Time (GMT)
User entered '21 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	(b) (4)	19 Oct 2020 15:54:36
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	(b) (4)	30 Sep 2020 20:28:16
User entered '21 Sep 2020'	Breanna Galibert (b) (4)	(b) (4)	30 Sep 2020 20:27:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Oct 2020 15:54:36
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 20:28:16
User entered 'Urine (URINE)'	Breanna Galibert (b) (4)	30 Sep 2020 20:27:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Oct 2020 15:54:36
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	30 Sep 2020 20:28:16
User entered 'Negative (NEGATIVE)'	Breanna Galibert (b) (4)	30 Sep 2020 20:27:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Was FSH sample collected?](#)

Audit	User		Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	(b) (4)	19 Oct 2020 15:54:36
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	(b) (4)	30 Sep 2020 20:28:16
User entered 'No (N)'	Breanna Galibert (b) (4)	(b) (4)	30 Sep 2020 20:27:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:27:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:27:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 20:27:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

If No, reason not given

Audit	User	Time (GMT)
User closed query 'Per CDM: Participant was not given treatment due to "Confirmed COVID-19"; however an AE has not been recorded. Please review and update all relevant eCRFs. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:48:54
Query 'Per CDM: Participant was not given treatment due to "Confirmed COVID-19"; however an AE has not been recorded. Please review and update all relevant eCRFs. Thank you.' answered with 'Per Investigator: Per CRA, no AE needed for baseline positive COVID-19 PCR swab at screening visit.' (Site from DM).	Any Penly (b) (4)	02 Nov 2020 18:48:13
User opened query 'Per CDM: Participant was not given treatment due to "Confirmed COVID-19"; however an AE has not been recorded. Please review and update all relevant eCRFs. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:04:17
User entered 'Confirmed COVID-19 (COVID)'	Breanna Galibert (b) (4)	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:55:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:53:12

US3812267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:53:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:53:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:30'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:53:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 09:30'	System	19 Oct 2020 15:53:44

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4)	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:35'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 09:35'	System	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 15:54:07

US3812267

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:37:06

US3812267

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:37:06

US3812267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:33:04

US3812267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:33:04

US3812267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:33:04

US3812267

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Inadvertent error site did not contact for Karen Knapp SCD38'	(b) (4) (b) (4)	01 Nov 2020 21:33:04

US3812267

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:37:13

US3812267

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:37:13

US3812267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:37:24

US3812267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:37:24

US3812267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:37:24

US3812267

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:37:24

US3812267

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:37:29

US3812267

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:37:29

US3812267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 15:12:04

US3812267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 15:12:04

US3812267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 15:12:04

US3812267

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 15:12:04

US3812267

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 15:12:09

US3812267

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 15:12:09

US3812267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:57:47

US3812267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:57:47

US3812267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:57:47

US3812267

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:55:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	19 Oct 2020 15:57:47

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '08:39'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '19 Oct 2020 08:39'	System	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

Pulse (xxx)

Audit	User	Time (GMT)
User entered '80'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '14'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '80'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:55:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Oct 2020 15:58:24

US3812267

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:35

US3812267

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:35

US3812267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:51

US3812267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:51

US3812267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:00'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:58:51

US3812267

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '19 Oct 2020 09:00'	System	19 Oct 2020 15:58:51

US3812267

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Oct 2020 15:59:28

US3812267

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:59:28

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 64'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-10-26T09:21:20', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '1bb0254a-adbe-41f4-8090-10bc2cef43b0'	System	26 Oct 2020 14:21:33
User entered 'No (N)'	System	26 Oct 2020 14:21:33

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-10-26T09:21:26', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '1bb0254a-adbe-41f4-8090-10bc2cef43b0'	System	26 Oct 2020 14:21:33
User entered 'No (N)'	System	26 Oct 2020 14:21:33

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-10-26T09:21:31', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '1bb0254a-adbe-41f4-8090-10bc2cef43b0'	System	26 Oct 2020 14:21:33
User entered '26 Oct 2020 09:21:31'	System	26 Oct 2020 14:21:33

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 71'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-02T07:15:22', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '0a6159b8-c86a-4f8a-a734-9dd76026c745'	System	02 Nov 2020 13:15:31
User entered 'No (N)'	System	02 Nov 2020 13:15:31

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-02T07:15:26', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '0a6159b8-c86a-4f8a-a734-9dd76026c745'	System	02 Nov 2020 13:15:31
User entered 'No (N)'	System	02 Nov 2020 13:15:31

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-02T07:15:29', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '0a6159b8-c86a-4f8a-a734-9dd76026c745'	System	02 Nov 2020 13:15:31
User entered '02 Nov 2020 07:15:29'	System	02 Nov 2020 13:15:31

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered 'Day 78'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-09T15:50:39', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '578217ef-88a8-43d7-96b7-f9b4a7e83c41'	System	09 Nov 2020 21:50:50
User entered 'No (N)'	System	09 Nov 2020 21:50:50

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-09T15:50:42', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '578217ef-88a8-43d7-96b7-f9b4a7e83c41'	System	09 Nov 2020 21:50:50
User entered 'No (N)'	System	09 Nov 2020 21:50:50

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-09T15:50:45', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '578217ef-88a8-43d7-96b7-f9b4a7e83c41' User entered '09 Nov 2020 15:50:45'	System	09 Nov 2020 21:50:50
	System	09 Nov 2020 21:50:50

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 15:41:23

US3812267

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 15:41:23
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 15:41:23

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-23T07:44:31', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '36919c11-ca42-48ec-856e-b3a6bf149fae' User entered 'No (N)'	System	23 Nov 2020 13:44:41

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-23T07:44:34', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '36919c11-ca42-48ec-856e-b3a6bf149fae'	System	23 Nov 2020 13:44:41
User entered 'No (N)'	System	23 Nov 2020 13:44:41

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAD8B589-E406-4557-AE7D-1B38B1492436)', Time: '2020-11-23T07:44:38', User OID: 'PatientReportedOutcome (US3812267)', ODM File OID: '36919c11-ca42-48ec-856e-b3a6bf149fae' User entered '23 Nov 2020 07:44:38'	System	23 Nov 2020 13:44:41
	System	23 Nov 2020 13:44:41

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:04:32

US3812267

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:55:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:32
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:04:32

US3812267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	16 Nov 2020 17:07:47

US3812267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Karen Knapp (b) (4) (b) (4)	16 Nov 2020 17:07:47

US3812267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	16 Nov 2020 17:07:47

US3812267

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:55:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	16 Nov 2020 17:07:47

US3812267

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	16 Nov 2020 17:07:53

US3812267

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:55:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 17:07:53

US3812267

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:38

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Lyly Dang (b) (4)	04 Sep 2020 00:24:06

US3812267

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:38

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '09:07'	Lyly Dang (b) (4)	04 Sep 2020 00:24:06

US3812267

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 09:07'	System	04 Sep 2020 00:24:06

US3812267

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:38

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Lyly Dang (b) (4) Scheduled)'	(b) (4)	04 Sep 2020 00:24:06

US3812267

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:55:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 00:24:06

US3812267

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:55:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	18 Oct 2020 13:09:24

US3812267

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:55:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:43:41
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 17:31:10

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:44:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 23:44:53
Data point term sent to Coder	System	19 Nov 2020 23:44:38
User entered 'WORSENING ANXIETY'	Breanna Galibert (b) (4)	19 Nov 2020 23:44:29
	(b) (4)	

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[None](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 23:44:29

US3812267

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:55:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 23:44:29

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:55:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:25:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:31:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:31:51
Data point term sent to Coder Coding entries removed.	System	01 Nov 2020 21:30:33
	Karen Knapp (b) (4)	01 Nov 2020 21:30:00
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 18:28:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Aug 2020 18:28:48
Data point term sent to Coder User entered 'MIRENA IUD'	System	29 Aug 2020 18:27:40
	Karen Knapp (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'BIRTH CONTROL'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '52' reason for change: Per Query Resolution	Anya Penly (b) (4)	12 Nov 2020 22:02:41
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage and/or unit or provide explanation for alternate dosage and/or unit.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 00:00:34
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage and/or unit or provide explanation for alternate dosage and/or unit.' answered with 'updated' (Site from DM).	Karen Knapp (b) (4)	01 Nov 2020 21:30:25
User entered '1' reason for change: Per Query Resolution	Karen Knapp (b) (4)	01 Nov 2020 21:28:07
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose and unit for this medication. Please correct the dosage and/or unit or provide explanation for alternate dosage and/or unit.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:46:44
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 12:27:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 12:27:14
User entered '20' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	04 Sep 2020 12:27:14
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 18:26:27
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Anya Penly (b) (4)	12 Nov 2020 22:02:41
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 12:27:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 12:27:14
User entered 'Other (OTHER)' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	04 Sep 2020 12:27:14
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Aug 2020 18:26:27
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Anya Penly (b) (4)	12 Nov 2020 22:02:41
User entered 'unit' reason for change: Per Query Resolution	Karen Knapp (b) (4)	01 Nov 2020 21:28:07
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	04 Sep 2020 12:27:22
User entered 'mcg' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	04 Sep 2020 12:27:22
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	04 Sep 2020 12:27:14
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Requery: Per previous query response " Updated conmed per Investigator"; however, please provide location of update such as log line number. Thank you.	(b) (4), (b) (6)	23 Nov 2020 14:16:10
' (Site from DM). Query 'Per CDM Requery: Per previous query response " Updated conmed per Investigator"; however, please provide location of update such as log line number. Thank you.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:46:11
' answered with 'UPDATED CONMED PER INVESTIGATOR LOG LINE NUMBER 1' (Site from DM). User opened query 'Per CDM Requery: Per previous query response " Updated conmed per Investigator"; however, please provide location of update such as log line number. Thank you.	(b) (4), (b) (6)	18 Nov 2020 14:23:55
' (Site from DM). Query 'Per CDM requery: Per CDM: Per previous query response " Updated conmed per Investigator"; however, please provide location of update such as log line number. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:23:15
User opened query 'Per CDM requery: Per CDM: Per previous query response " Updated conmed per Investigator"; however, please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:23:06
User closed query 'Per CDM: Site has recorded Mirena, a levonorgestrel-releasing intrauterine device. Please verify if standard daily release rate is 20 mcg/day, and if yes, update Frequency field to daily, and update Dose per Administration to 20 mcg/day. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:22:29

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

Frequency

Audit	User	Time (GMT)
Query 'Per CDM: Site has recorded Mirena, a levonorgestrel-releasing intrauterine device. Please verify if standard daily release rate is 20 mcg/day, and if yes, update Frequency field to daily, and update Dose per Administration to 20 mcg/day. Thank you.' answered with 'Updated conmed per Investigator' (Site from DM).	Anya Penly (b) (4) (b) (4)	12 Nov 2020 22:02:56
User entered 'other (OTHER)' reason for change: Per Query Resolution	Anya Penly (b) (4) (b) (4)	12 Nov 2020 22:02:41
Query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please update data accordingly. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 00:00:12
User opened query 'Per CDM: Site has recorded Mirena, a levonorgestrel-releasing intrauterine device. Please verify if standard daily release rate is 20 mcg/day, and if yes, update Frequency field to daily, and update Dose per Administration to 20 mcg/day. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 00:00:05
User opened query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please update data accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:21:23
User closed query 'Per DM CLR: Please review frequency = ONCE, as the medication remains ongoing. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:19:57
User entered 'once (ONCE)' reason for change: Per Query Resolution	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:28:07
Query 'Per DM CLR: Please review frequency = ONCE, as the medication remains ongoing. Please confirm and update as appropriate, otherwise clarify.' answered with 'Updated' (Site from DM).	Lyly Dang (b) (4)	26 Oct 2020 17:10:09
User entered 'once daily (QD)' reason for change: Data Entry Error	Lyly Dang (b) (4)	26 Oct 2020 17:09:56
User opened query 'Per DM CLR: Please review frequency = ONCE, as the medication remains ongoing. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 10:33:42
User entered 'once (ONCE)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'every 5 years' reason for change: Per Query Resolution	Anya Penly (b) (4)	12 Nov 2020 22:02:41
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:30:00
User entered 'Vaginal (VAGINAL)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'intrauterine' reason for change: Data Entry Error	Karen Knapp (b) (4)	01 Nov 2020 21:30:00
User entered empty.	Karen Knapp (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:28:07
User entered '1'	System	26 Oct 2020 17:09:56
User entered empty.	System	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:28:07
User entered '1'	System	26 Oct 2020 17:09:56
User entered empty.	System	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Nov 2020 21:28:07
User entered '804 (804)'	System	26 Oct 2020 17:09:56
User entered empty.	System	29 Aug 2020 18:26:27

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 12:30:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 12:30:37
Data point term sent to Coder	System	04 Sep 2020 12:29:22
User entered 'Alprazolam'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'Anxiety'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '.25'	Maureen Dempsey (b) (4) (b) (4)	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Maureen Dempsey (b) (4) (b) (4)	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '01 Mar 2020'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Maureen Dempsey (b) (4) (b) (4)	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	14 Oct 2020 15:52:21
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Oct 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	19 Nov 2020 23:47:07
User entered '20 Aug 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	14 Oct 2020 15:52:21
User entered empty.	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Maureen Dempsey (b) (4)	04 Sep 2020 12:28:52
	(b) (4)	

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 12:28:52

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:55:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:55:36
Data point term sent to Coder	System	14 Oct 2020 15:54:06
User entered 'influenza vaccine'	Breanna Galibert (b) (4) (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4) (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza prophylaxis'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'dose'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Route of administration](#)

Audit	User		Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert	(b) (4)	14 Oct 2020 15:53:42
	(b) (4)		
DataPoint activated with code reason code Data required.	Breanna Galibert	(b) (4)	14 Oct 2020 15:52:51
	(b) (4)		
DataPoint inactivated with code reason code Data not required.	Breanna Galibert	(b) (4)	30 Sep 2020 20:29:40
	(b) (4)		

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4)	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:53:42
DataPoint activated with code reason code Data required.	Breanna Galibert (b) (4)	14 Oct 2020 15:52:51
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	30 Sep 2020 20:29:40

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:49:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:49:54
Data point term sent to Coder	System	19 Nov 2020 23:48:41
User entered 'ALPRAZOLAM'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING ANXIETY/ANXIETY'	Breanna Galibert (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.25'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 23:47:57

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:42:53
Data point term sent to Coder	System	19 Nov 2020 23:49:42
User entered 'LORAZEPAM'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 15:07:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 15:07:49
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	20 Nov 2020 15:07:49
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:49:04
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING ANXIETY'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:49:04

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:42:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:42:52
Data point term sent to Coder	System	19 Nov 2020 23:49:42
User entered 'LORAZEPAM'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING ANXIETY'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:55:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:49:30

US3812267

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:55:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 17:31:17

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Visit](#)

Audit	User	Time (GMT)
User entered 'Visit 2 Day 29 (VISIT2)'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Visit Date](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Demographics](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Enrollment](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Medical History Summary](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Medical History](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Physical Examination](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Childbearing Potential](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Randomization](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Exposure](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Saliva Collection](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Symptom Log](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[COVID-19 Contact](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Risk of Exposure](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Safety Call](#)

Audit	User	Time (GMT)
User entered '1'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[All](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
User closed query 'There are no selections for Category. Please select at least one category.' (Site from System).	System	01 Nov 2020 21:35:51
Query 'There are no selections for Category. Please select at least one category.' answered by data change (Site from System).	System	01 Nov 2020 21:35:51
User opened query 'There are no selections for Category. Please select at least one category.' (Site from System).	System	01 Nov 2020 21:34:53
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Study Treatment not given](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Missed Visit](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Missed Assessment](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Visit performed out of window](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Assessment performed out of window](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Per Query Resolution	Karen Knapp (b) (4)	01 Nov 2020 21:35:51
User entered '0'	Karen Knapp (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Other, specify](#)

Audit	User	Time (GMT)
User entered 'Missed safety call' reason for change:	Karen Knapp (b) (4)	01 Nov 2020 21:35:51
Per Query Resolution	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	01 Nov 2020 21:34:53
	(b) (4)	

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Clinical site closed](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Travel restrictions](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
User entered '1'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:55:38

[Participant decision](#)

Audit	User	Time (GMT)
User entered '0'	Karen Knapp (b) (4) (b) (4)	01 Nov 2020 21:34:53

US3812267

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:55:38

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Lyly Dang (b) (4)	20 Nov 2020 22:50:42

US3812267

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:55:38

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Lyly Dang (b) (4)	20 Nov 2020 22:50:42

US3812267

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:55:38

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

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	20 Nov 2020 22:50:42