

US3522077 (Prod: Henry Ford Health System)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:31:41

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US3522077

Form: Participant Creation

Generated On: 26 Nov 2020 09:31:41

[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 09:31:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 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 09:31:41

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	62
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 09:31:41

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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 09:31:41

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:41

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

Condition	MIGRAINES
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

Condition	NEPHROLITHIASIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:50 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:50
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	209.5 lb
BMI (<i>xxx.x</i>)	31.00243 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☒	No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐	No ☒
Other	Yes ☐	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 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 09:31:41

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 102915

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:41

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:50
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 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 09:31:41

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 11:15
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 10:45

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 09:31:41

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	11 AUG 2020
Collection time (<i>00:00-23:59</i>)	9:47 (24 HR)
Collection date and time (derived)	11 AUG 2020 9:47

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:41

Collection date (<i>dd MMM yyyy</i>)			11 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	10:13	11 AUG 2020 10:13
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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 09:31:41

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

11 AUG 2020 11:16

PC Open Date & Time

11 AUG 2020 11:05

PC Close Date & Time

11 AUG 2020 13:35

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 11 AUG 2020 17:04

PC Open Date & Time 11 AUG 2020 14:30

PC Close Date & Time 12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

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

97.3 °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

12 AUG 2020 14:26

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 13 AUG 2020 12:00

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 23:59

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 12:24

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 07:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 20:39

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

11 AUG 2020 11:16

PC Open Date & Time

11 AUG 2020 11:05

PC Close Date & Time

11 AUG 2020 13:35

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

11 AUG 2020 17:04

PC Open Date & Time

11 AUG 2020 14:30

PC Close Date & Time

12 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

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

12 AUG 2020 14:27

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

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

13 AUG 2020 12:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

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

14 AUG 2020 23:59

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

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

15 AUG 2020 12:24

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

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

17 AUG 2020 07:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

17 AUG 2020 20:39

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 11:18
PC Open Date & Time	11 AUG 2020 11:05
PC Close Date & Time	11 AUG 2020 13:35

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 17:04
PC Open Date & Time	11 AUG 2020 14:30
PC Close Date & Time	12 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	12 AUG 2020 14:27
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	13 AUG 2020 12:01
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	15 AUG 2020 00:00
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	15 AUG 2020 12:24
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	17 AUG 2020 07:05
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	17 AUG 2020 20:39
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3522077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CALLED BUT PT. DID NOT
ANSWER THE PHONE

If Contact Not Made, please provide Comments

US3522077

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

PATIENT DID NOT ANSWER;
VOICEMAIL WAS LEFT- WILL
CALL AGAIN LATER TODAY

If Contact Not Made, please provide Comments

US3522077

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE RISK

US3522077

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:32
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:25
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3522077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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)	10 SEP 2020
What was the treatment time? (00:00-23:59)	12:55 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 12:55
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

US3522077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:50 (24 HR)
Collection date and time (derived)	10 SEP 2020 12:50

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:41

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:52	10 SEP 2020 12:52
Nasopharyngeal Swab 2	No		

US3522077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 13:16

PC Open Date & Time

10 SEP 2020 13:15

PC Close Date & Time

10 SEP 2020 15:45

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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	10 SEP 2020 19:41
PC Open Date & Time	10 SEP 2020 16:40
PC Close Date & Time	11 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:25

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 12 SEP 2020 23:59

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 07:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

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 ☒

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 16 SEP 2020 06:43

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 06:51

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

10 SEP 2020 13:17

PC Open Date & Time

10 SEP 2020 13:15

PC Close Date & Time

10 SEP 2020 15:45

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

10 SEP 2020 19:42

PC Open Date & Time

10 SEP 2020 16:40

PC Close Date & Time

11 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

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

11 SEP 2020 15:25

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

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

12 SEP 2020 23:59

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

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

15 SEP 2020 07:20

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

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

16 SEP 2020 06:43

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

17 SEP 2020 06:51

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 13:17
PC Open Date & Time	10 SEP 2020 13:15
PC Close Date & Time	10 SEP 2020 15:45

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 19:42
PC Open Date & Time	10 SEP 2020 16:40
PC Close Date & Time	11 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	11 SEP 2020 15:25
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	12 SEP 2020 23:59
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

		Yes ☐
PC Time stamp		
PC Open Date & Time		13 SEP 2020 12:00
PC Close Date & Time		14 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	15 SEP 2020 07:20
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	16 SEP 2020 06:43
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

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 ☒

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

Yes ☐	
PC Time stamp	17 SEP 2020 06:51
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3522077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

VOICEMAIL LEFT

If Contact Not Made, please provide Comments

US3522077

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 SEP 2020

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

Comments 1ST ATTEMPT 24 SEP 2020, 2ND
ATTEMPT 29 SEP 2020, 3RD
If Contact Not Made, please provide Comments ATTEMPT TODAY

US3522077

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

E-DIARY FROM DAY 8 AND HE
HAD NO AES AT THAT POINT.
SINCE THEN, NO ONGOING OR
NEW AE REPORTED, NO NEW
ILLNESS OR HOSPITAL VISITS;
NO CHANGES IN HEALTH
STATUS, MEDICATIONS, OR
COVID-19 EXPOSURE RISK

US3522077

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:50 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:50
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3522077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	12 OCT 2020
Collection time (<i>00:00-23:59</i>)	08:56 (24 HR)
Collection date and time (derived)	12 OCT 2020 08:56

US3522077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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	11 OCT 2020 00:01:38
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	25 OCT 2020 00:02:22
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 18:30:03

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

15 NOV 2020 03:33:10

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

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22 FEB 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

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01 MAR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

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08 MAR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

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15 MAR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 SEP 2021 00:01

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20 SEP 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 FEB 2022 00:01

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07 FEB 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 FEB 2022 00:01

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14 FEB 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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17 FEB 2022 00:01

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21 FEB 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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28 FEB 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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°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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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21 MAR 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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24 MAR 2022 00:01

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28 MAR 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 MAR 2022 00:01

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04 APR 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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11 APR 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 APR 2022 00:01

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18 APR 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 APR 2022 00:01

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02 MAY 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 MAY 2022 00:01

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09 MAY 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUL 2022 00:01

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11 JUL 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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°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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3522077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

"NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK."

US3522077

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

US3522077

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522077

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:31:41

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

US3522077

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:31:41

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522077

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:41

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

AEID	USA-US131-2020-MRNA-1273-P30 1000009
Adverse event	PULMONARY EMBOLISMS (RIGHT MAIN PULMONARY ARTERY, LEFTS LOWER LOBAR BRANCH)
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)	15 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)	19 OCT 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	True
Hospital Admission Date (dd MMM yyyy)	17 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	19 OCT 2020
Admitted to ICU?	Yes ☐ No ☒

v6.020 DTW (1102)

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US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

	Unknown	☐
Number of Days in ICU		
Persistent or significant disability or incapacity	False	
Congenital anomaly or birth defect	False	
Other medically important event	False	
Relationship to investigational product	Not Related	☒
	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		

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

FROM DISCHARGE:
62 YO. PRESENTED TO THE
HOSPITAL FOR LEFT
FLANK/UPPER
ABDOMINAL PAIN 10/17/2020.
SYMPTOMS STARTED 2 DAYS
PRIOR (10/15/2020). INITIALLY
DESCRIBED AS AN ACHY LIKE
SENSATION ON THE LEFT
UPPER ABDOMINAL/FLANK
REGION. THOUGHT IT WAS
LIKELY MUSCULOSKELETAL.
THE FOLLOWING DAY IS A
LITTLE BIT WORSE TOOK
CELEBREX. THAT EVENING
THE PAIN GOT SEVERE WITH
SOME DIFFICULTY WITH
BREATHING. PAIN
MEDICATION DID NOT
ALLEVIATE THE SYMPTOM. HE
THOUGHT HE WAS HAVING A
KIDNEY STONE GIVEN HIS
HISTORY OF
NEPHROLITHIASIS. HE STATES
WHEN EMS ARRIVED AND HE
WAS GIVEN FENTANYL THAT
HELPS ALLEVIATE HIS
SYMPTOMS. HE DENIES ANY
LONG TRAVELS PRIOR TO HIS
SYMPTOMS STARTING. DENIES
FAMILY HISTORY OF BLOOD
CLOTS. DENIES RECENT
SURGERY, IMMOBILITY.
VITALS ON ARRIVAL WITH
TACHYCARDIA. LABORATORY
STUDIES WITH SLIGHT BNP
ELEVATION, SLIGHT

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

LEUKOCYTOSIS, SLIGHT
NORMOCYTIC ANEMIA. ?CT
IMAGING WITH RESULTS
BELOW REVEALING PE AND
OPACITIES CONCERNING FOR
POSSIBLE INFARCTION OR
ATELECTASIS. ?PATIENT WAS
STARTED ON HEPARIN,
AVELOX ORDERED, COVID-19
SWAB DONE, AND HE WAS
ADMITTED FOR FURTHER
MANAGEMENT.
HEMODYNAMICALLY STABLE.
BP NORMAL RANGE. NOT
REQUIRING OXYGEN
PRESENTLY.?NO RIGHT
HEART?STRAIN NOTED ON
IMAGING. TROP <18, BNP
58??.?STARTED
ON?ENOXAPARIN.??2D
ECHO?SHOWED NORMAL EF
WITHOUT RV STRAIN.
?PULMONARY WAS
CONSULTED. ?BILATERAL
VENOUS DOPPLER?WERE
NEGATIVE FOR ANY ACUTE
DVT.??IT IS NOT CLEAR WHY
THIS PATIENT HAD LARGE
PULMONARY
EMBOLISM?HOWEVER HE DID
HAVE SEDENTARY LIFESTYLE
OVER THE LAST 6 MONTHS. ?HE
IS UP-TO-DATE ON HIS CANCER
SCREENING. ?HE HAS NO
RESPIRATORY ILLNESS TO
SUGGEST COVID-19. ?HIS
COVID-19 WAS NEGATIVE?AND

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

HIS ANTIBODIES WERE
NEGATIVE AS WELL. ?HE WAS
SWITCHED TO ELIQUIS.
?ADVISED TO FOLLOW-UP WITH
HEMATOLOGY FOR
HYPERCOAGULABLE WORKUP.
DISCHARGED 10/19/2020.
HEMATOLOGIC CONSULT WAS
COMPLETED ON 09 NOV 2020.
RECOMMENDED THAT HE
CONTINUE WITH ELIQUIS.
CURRENTLY ON ELIQUIS 5 MG
TWICE A DAY (PER EPIC
STARTED ON 04 NOV 2020)

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

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:31:41

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

Yes ☒

No ☐

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

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINES
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

	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)		
Start date completely unknown		True
Ongoing?		Yes ☐
		No ☒
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
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 ☒

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	VERAPAMIL
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINES
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

	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)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	EVOLOCUMAB
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
Dose per administration	140
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	ONCE EVERY 14 DAYS Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

	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)		
Start date completely unknown		True
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 ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	FLUBLOK RIV 4
Prophylaxis	Yes ☒ No ☐
Indication	PREVENTION OF INFLUENZA
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

	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)		18 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 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 ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	ENOXAPARIN
Prophylaxis	Yes ☐ No ☒
Indication	PULMONARY EMBOLISMS
Dose per administration	90
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 12 HOURS Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

	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)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 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	☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	HEPARIN
Prophylaxis	Yes ☐ No ☒
Indication	PULMONARY EMBOLISM
Dose per administration	25000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS IN DEXTROSE
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	CONTINUOUS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

	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)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 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 ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	AVELOX
Prophylaxis	Yes ☐ No ☒
Indication	PULMONARY EMBOLISM
Dose per administration	400
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

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)	17 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 17 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 ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	PULMONARY EMBOLISMS
Dose per administration	VARIABLE
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	DOSE VARIED BETWEEN 975 MG AND 650 MG
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	EVERY 8 HOURS
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

	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)	18 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		19 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 ☐	

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	PULMONARY EMBOLISM
Dose per administration	4
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 ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

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)	17 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	18 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	PULMONARY EMBOLISM
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

	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)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 OCT 2020
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	☒

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ☒
Indication	PULMONARY EMBOLISMS
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
TWO TABLETS TWICE DAILY FOR 7 DAYS, ONE TABLET TWICE DAILY ONGOING	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINE
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
ONCE IN MORNING, TWICE AT NIGHT	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

	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)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3522077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:31:41

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3522077

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:31:41

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3522077

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:31:41

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 ☐

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

SAEID	USA-US131-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:41

SAEID	USA-US131-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	28/OCT/2020 17:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:41

SAEID	USA-US131-2020-MRNA-1273-P301000009
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	10/NOV/2020 19:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3522077 (Prod: Henry Ford Health System)

US3522077

Form: Participant Creation

Generated On: 26 Nov 2020 09:31:41

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3522077'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 13:29:56

US3522077

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:02

US3522077

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 13:29:57

US3522077

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:02

US3522077

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 13:35:02

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 13:29:57

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Age](#)

Audit	User	Time (GMT)
User entered '62'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '62'	System	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[White](#)

Audit	User	Time (GMT)
User entered '1'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:31:41

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:37

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:49

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 13:29:57

US3522077

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:31:41

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:35:54

US3522077

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:35:54

US3522077

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:31:41

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Query 'Notes on 17Oct2020 indicate that subject has a history of kidney stones and as a result had flank pain. Please document history of kidney stones as a medical history.' answered with 'history of kidney stones has been added' (Site from CRA).	Jelena Verkler (b) (4) (b) (4)	12 Nov 2020 15:14:45
User opened query 'Notes on 17Oct2020 indicate that subject has a history of kidney stones and as a result had flank pain. Please document history of kidney stones as a medical history.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	10 Nov 2020 17:48:33
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:38:22

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 17:47:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 17:47:19
Data point term sent to Coder	System	13 Aug 2020 17:45:48
User entered 'Hyperlipidemia' reason for change: Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 17:45:39
Data point term sent to Coder	System	11 Aug 2020 13:40:01
User entered 'mild coronary artery disease'	Alandra White (b) (4)	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:28:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:28:07
User entered 'Yes (Y)' reason for change: Per Query Resolution	Alandra White (b) (4)	11 Aug 2020 14:28:07
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 13:39:03
User entered empty.	Alandra White (b) (4)	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:39:03

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 17:47:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 17:47:20
Data point term sent to Coder	System	13 Aug 2020 17:46:52
User entered 'Migraines'	Sharon Mathys (b) (4)	13 Aug 2020 17:46:21
	(b) (4)	

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 17:46:21

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 15:14:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 15:14:51
Data point term sent to Coder	System	12 Nov 2020 15:14:37
User entered 'Nephrolithiasis'	Jelena Verkler (b) (4)	12 Nov 2020 15:14:29
	(b) (4)	

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	Jelena Verkler (b) (4) (b) (4)	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jelena Verkler (b) (4) (b) (4)	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jelena Verkler (b) (4) (b) (4)	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	Jelena Verkler (b) (4) (b) (4)	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jelena Verkler (b) (4) (b) (4)	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 15:14:29

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 13:52:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 13:52:57
User entered 'Yes (Y)' reason for change: Per Query Resolution	Alandra White (b) (4)	11 Aug 2020 13:52:57
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 13:52:50
User entered empty.	Alandra White (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '09:50'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 09:50'	System	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '69' in	Alandra White (b) (4)	11 Aug 2020 13:52:50
DataPoint set to visible.	(b) (4) System	11 Aug 2020 13:35:54

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '209.5' lb	Alandra White (b) (4)	11 Aug 2020 13:52:50
DataPoint set to visible.	(b) (4) System	11 Aug 2020 13:35:54

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '31.00243'	System	16 Sep 2020 23:51:13
User entered '31.0'	System	11 Aug 2020 13:52:50
DataPoint set to visible.	System	11 Aug 2020 13:35:54

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Aug 2020 13:52:50
DataPoint set to visible.	System	11 Aug 2020 13:35:54

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:18
User entered '97.6' F	Alandra White (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 14:44:09
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'done' (Site from DM).	Tyler Prentiss (b) (4) (b) (4)	24 Aug 2020 20:31:19
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	24 Aug 2020 20:31:14
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 04:59:25
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	14 Aug 2020 12:41:18
User entered 'Other (Other)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:18
User entered 'temporal'	Alandra White (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:18
User entered '70'	Alandra White (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:18
User entered '16'	Alandra White (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:18
User entered '129'	Alandra White (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:18
User entered '80'	Alandra White (b) (4)	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 13:52:50

US3522077

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:15:49

US3522077

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 17:44:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 16:35:38
User entered '11 Aug 2020'	Alandra White (b) (4)	11 Aug 2020 14:15:49

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '1'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

Other

Audit	User	Time (GMT)
User entered '0'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:31:41

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:37:05

US3522077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:36:07

US3522077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:36:07

US3522077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:36:07

US3522077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 13:36:07

US3522077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 13:34:47

US3522077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:30:06
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:30:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 13:34:47
User entered '102915' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 13:34:47

US3522077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:41

[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) [REDACTED]	11 Aug 2020 13:34:47

US3522077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:41

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)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:36:19

US3522077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:36:19

US3522077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:36:19

US3522077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:36:19

US3522077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:31:41

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:36:19

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:41

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:35
User entered '69' in	Alandra White (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:41

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:35
User entered '95' kg	Alandra White (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:41

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:35
User entered '69' in	Alandra White (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:41

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:35
User entered '95' kg	Alandra White (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '09:50'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 09:50'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '16'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '129'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '80'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:41

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:35
User entered '69' in	Alandra White (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:31:41

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	14 Aug 2020 12:41:35
User entered '95' kg	Alandra White (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:51:31
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 15:15:41
User entered '11:15'	Alandra White (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:15'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '18'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '125'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '78'	Alandra White (b) (4) (b) (4)	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 15:15:41

US3522077

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 15:52:27
User entered 'Yes (Y)'	Alandra White (b) (4)	11 Aug 2020 14:15:38

US3522077

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 15:52:27
User entered '11 Aug 2020'	Alandra White (b) (4)	11 Aug 2020 14:15:38

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10:45'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:45'	System	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 14:49:15

US3522077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:13:04

US3522077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:13:04

US3522077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '9:47' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 16:36:13
User entered '10:13'	Alandra White (b) (4)	11 Aug 2020 14:13:04

US3522077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 9:47'	System	01 Oct 2020 16:36:13
User entered '11 Aug 2020 10:13'	System	11 Aug 2020 14:13:04

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:41

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:13' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 16:36:24
User entered '09:47'	Alandra White (b) (4)	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 10:13'	System	01 Oct 2020 16:36:24
User entered '11 Aug 2020 09:47'	System	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:41

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 14:12:50

US3522077

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 14:51:39

US3522077

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 14:51:39

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:15:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'bcab8414-854f-4de7-8a9a-db030d0892aa'	System	11 Aug 2020 15:16:06
User entered 'Yes (Y)'	System	11 Aug 2020 15:16:06

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:15:49', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'bcab8414-854f-4de7-8a9a-db030d0892aa'	System	11 Aug 2020 15:16:06
User entered '97.5'	System	11 Aug 2020 15:16:06

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:15:54', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'bcab8414-854f-4de7-8a9a-db030d0892aa'	System	11 Aug 2020 15:16:06
User entered 'No (N)'	System	11 Aug 2020 15:16:06

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:16:01', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'bcab8414-854f-4de7-8a9a-db030d0892aa'	System	11 Aug 2020 15:16:06
User entered '11 Aug 2020 11:16'	System	11 Aug 2020 15:16:06

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:05'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:35'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:03:58', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0ad0fb26-f2f9-4040-b1bb-afaeed007c4d'	System	11 Aug 2020 21:04:16
User entered 'Yes (Y)'	System	11 Aug 2020 21:04:16

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:07', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0ad0fb26-f2f9-4040-b1bb-afaeed007c4d' User entered '97.7'	System	11 Aug 2020 21:04:16
	System	11 Aug 2020 21:04:16

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:11', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0ad0fb26-f2f9-4040-b1bb-afaeed007c4d'	System	11 Aug 2020 21:04:16
User entered 'No (N)'	System	11 Aug 2020 21:04:16

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:14', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0ad0fb26-f2f9-4040-b1bb-afaeed007c4d'	System	11 Aug 2020 21:04:16
User entered '11 Aug 2020 17:04'	System	11 Aug 2020 21:04:16

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 14:30'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 2'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:26:33', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '6e496def-cec5-4e75-b052-8f4f87860602'	System	12 Aug 2020 18:26:47
User entered 'Yes (Y)'	System	12 Aug 2020 18:26:47

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:26:39', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '6e496def-cec5-4e75-b052-8f4f87860602'	System	12 Aug 2020 18:26:47
User entered '97.3'	System	12 Aug 2020 18:26:47

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:26:42', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '6e496def-cec5-4e75-b052-8f4f87860602'	System	12 Aug 2020 18:26:47
User entered 'No (N)'	System	12 Aug 2020 18:26:47

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:26:45', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '6e496def-cec5-4e75-b052-8f4f87860602'	System	12 Aug 2020 18:26:47
User entered '12 Aug 2020 14:26'	System	12 Aug 2020 18:26:47

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 3'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:00:39', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '3791feb5-8421-4111-896c-51c19e95f10c'	System	13 Aug 2020 16:00:56
User entered 'Yes (Y)'	System	13 Aug 2020 16:00:56

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:00:45', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '3791feb5-8421-4111-896c-51c19e95f10c'	System	13 Aug 2020 16:00:56
User entered '97.7'	System	13 Aug 2020 16:00:56

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:00:48', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '3791feb5-8421-4111-896c-51c19e95f10c'	System	13 Aug 2020 16:00:56
User entered 'No (N)'	System	13 Aug 2020 16:00:56

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:00:51', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '3791feb5-8421-4111-896c-51c19e95f10c'	System	13 Aug 2020 16:00:56
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 16:00:56

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 4'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:23', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'b1ba24af-8d50-4007-8b41-66158004ffb6'	System	15 Aug 2020 03:59:37
User entered 'Yes (Y)'	System	15 Aug 2020 03:59:37

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:29', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'b1ba24af-8d50-4007-8b41-66158004ffb6'	System	15 Aug 2020 03:59:37
User entered '98.0'	System	15 Aug 2020 03:59:37

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:32', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'b1ba24af-8d50-4007-8b41-66158004ffb6'	System	15 Aug 2020 03:59:37
User entered 'No (N)'	System	15 Aug 2020 03:59:37

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:34', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'b1ba24af-8d50-4007-8b41-66158004ffb6'	System	15 Aug 2020 03:59:37
User entered '14 Aug 2020 23:59'	System	15 Aug 2020 03:59:37

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 5'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:23:30', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'd67d0c2d-8b46-4f10-aef4-f8c45ea5aea0'	System	15 Aug 2020 16:24:15
User entered 'Yes (Y)'	System	15 Aug 2020 16:24:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:08', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'd67d0c2d-8b46-4f10-aef4-f8c45ea5aea0'	System	15 Aug 2020 16:24:15
User entered '98.0'	System	15 Aug 2020 16:24:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:11', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'd67d0c2d-8b46-4f10-aef4-f8c45ea5aea0'	System	15 Aug 2020 16:24:15
User entered 'No (N)'	System	15 Aug 2020 16:24:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:13', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'd67d0c2d-8b46-4f10-aef4-f8c45ea5aea0'	System	15 Aug 2020 16:24:15
User entered '15 Aug 2020 12:24'	System	15 Aug 2020 16:24:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 6'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:12', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '205d134b-df60-4e1a-ae65-0da0764ca0cb'	System	17 Aug 2020 11:05:39
User entered 'Yes (Y)'	System	17 Aug 2020 11:05:39

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:16', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '205d134b-df60-4e1a-ae65-0da0764ca0cb'	System	17 Aug 2020 11:05:39
User entered '98.0'	System	17 Aug 2020 11:05:39

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:18', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '205d134b-df60-4e1a-ae65-0da0764ca0cb'	System	17 Aug 2020 11:05:39
User entered 'No (N)'	System	17 Aug 2020 11:05:39

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:21', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '205d134b-df60-4e1a-ae65-0da0764ca0cb'	System	17 Aug 2020 11:05:39
User entered '17 Aug 2020 07:05'	System	17 Aug 2020 11:05:39

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 7'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:01', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'f25aa379-b3f9-4b5f-aa75-0094fc2aba05'	System	18 Aug 2020 00:39:12
User entered 'Yes (Y)'	System	18 Aug 2020 00:39:12

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:05', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'f25aa379-b3f9-4b5f-aa75-0094fc2aba05'	System	18 Aug 2020 00:39:12
User entered '98.0'	System	18 Aug 2020 00:39:12

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:08', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'f25aa379-b3f9-4b5f-aa75-0094fc2aba05'	System	18 Aug 2020 00:39:12
User entered 'No (N)'	System	18 Aug 2020 00:39:12

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:10', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'f25aa379-b3f9-4b5f-aa75-0094fc2aba05'	System	18 Aug 2020 00:39:12
User entered '17 Aug 2020 20:39'	System	18 Aug 2020 00:39:12

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:16:19', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a73d8e15-5702-451b-aea1-6cbd101fd2c4'	System	11 Aug 2020 15:16:38
User entered 'None (1)'	System	11 Aug 2020 15:16:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:16:23', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a73d8e15-5702-451b-aea1-6cbd101fd2c4'	System	11 Aug 2020 15:16:38
User entered 'No (N)'	System	11 Aug 2020 15:16:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:16:26', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a73d8e15-5702-451b-aea1-6cbd101fd2c4'	System	11 Aug 2020 15:16:38
User entered 'No (N)'	System	11 Aug 2020 15:16:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:16:31', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a73d8e15-5702-451b-aea1-6cbd101fd2c4'	System	11 Aug 2020 15:16:38
User entered 'None (1)'	System	11 Aug 2020 15:16:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:16:35', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a73d8e15-5702-451b-aea1-6cbd101fd2c4'	System	11 Aug 2020 15:16:38
User entered '11 Aug 2020 11:16'	System	11 Aug 2020 15:16:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:05'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:35'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:23', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9013ffce-61ba-45ed-841e-5861734da8e9'	System	11 Aug 2020 21:04:38
User entered 'None (1)'	System	11 Aug 2020 21:04:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:27', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9013ffce-61ba-45ed-841e-5861734da8e9'	System	11 Aug 2020 21:04:38
User entered 'No (N)'	System	11 Aug 2020 21:04:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:30', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9013ffce-61ba-45ed-841e-5861734da8e9'	System	11 Aug 2020 21:04:38
User entered 'No (N)'	System	11 Aug 2020 21:04:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:33', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9013ffce-61ba-45ed-841e-5861734da8e9'	System	11 Aug 2020 21:04:38
User entered 'None (1)'	System	11 Aug 2020 21:04:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:36', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9013ffce-61ba-45ed-841e-5861734da8e9'	System	11 Aug 2020 21:04:38
User entered '11 Aug 2020 17:04'	System	11 Aug 2020 21:04:38

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 14:30'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 2'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:26:49', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '520a4cb7-c330-4ec0-9926-16c6bb70166c'	System	12 Aug 2020 18:27:04
User entered 'None (1)'	System	12 Aug 2020 18:27:04

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:26:52', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '520a4cb7-c330-4ec0-9926-16c6bb70166c'	System	12 Aug 2020 18:27:04
User entered 'No (N)'	System	12 Aug 2020 18:27:04

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:26:55', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '520a4cb7-c330-4ec0-9926-16c6bb70166c'	System	12 Aug 2020 18:27:04
User entered 'No (N)'	System	12 Aug 2020 18:27:04

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:26:59', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '520a4cb7-c330-4ec0-9926-16c6bb70166c'	System	12 Aug 2020 18:27:04
User entered 'None (1)'	System	12 Aug 2020 18:27:04

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:01', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '520a4cb7-c330-4ec0-9926-16c6bb70166c'	System	12 Aug 2020 18:27:04
User entered '12 Aug 2020 14:27'	System	12 Aug 2020 18:27:04

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 3'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:00:54', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '7e52db06-f04d-4d88-97da-b31d6eed72ae'	System	13 Aug 2020 16:01:14
User entered 'None (1)'	System	13 Aug 2020 16:01:14

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:00:57', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '7e52db06-f04d-4d88-97da-b31d6eed72ae'	System	13 Aug 2020 16:01:14
User entered 'No (N)'	System	13 Aug 2020 16:01:14

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:00:59', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '7e52db06-f04d-4d88-97da-b31d6eed72ae'	System	13 Aug 2020 16:01:14
User entered 'No (N)'	System	13 Aug 2020 16:01:14

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:02', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '7e52db06-f04d-4d88-97da-b31d6eed72ae'	System	13 Aug 2020 16:01:14
User entered 'None (1)'	System	13 Aug 2020 16:01:14

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:05', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '7e52db06-f04d-4d88-97da-b31d6eed72ae'	System	13 Aug 2020 16:01:14
User entered '13 Aug 2020 12:01'	System	13 Aug 2020 16:01:14

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 4'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:38', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8ee21014-d47a-444f-970b-118df82c69bc'	System	15 Aug 2020 03:59:51
User entered 'None (1)'	System	15 Aug 2020 03:59:51

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:41', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8ee21014-d47a-444f-970b-118df82c69bc'	System	15 Aug 2020 03:59:51
User entered 'No (N)'	System	15 Aug 2020 03:59:51

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:43', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8ee21014-d47a-444f-970b-118df82c69bc'	System	15 Aug 2020 03:59:51
User entered 'No (N)'	System	15 Aug 2020 03:59:51

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:45', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8ee21014-d47a-444f-970b-118df82c69bc'	System	15 Aug 2020 03:59:51
User entered 'None (1)'	System	15 Aug 2020 03:59:51

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:47', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8ee21014-d47a-444f-970b-118df82c69bc'	System	15 Aug 2020 03:59:51
User entered '14 Aug 2020 23:59'	System	15 Aug 2020 03:59:51

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 5'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:16', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9b3a3222-f2b3-44d1-b2c5-175a2e97f983'	System	15 Aug 2020 16:24:28
User entered 'None (1)'	System	15 Aug 2020 16:24:28

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:19', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9b3a3222-f2b3-44d1-b2c5-175a2e97f983'	System	15 Aug 2020 16:24:28
User entered 'No (N)'	System	15 Aug 2020 16:24:28

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:21', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9b3a3222-f2b3-44d1-b2c5-175a2e97f983'	System	15 Aug 2020 16:24:28
User entered 'No (N)'	System	15 Aug 2020 16:24:28

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:23', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9b3a3222-f2b3-44d1-b2c5-175a2e97f983'	System	15 Aug 2020 16:24:28
User entered 'None (1)'	System	15 Aug 2020 16:24:28

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:25', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '9b3a3222-f2b3-44d1-b2c5-175a2e97f983'	System	15 Aug 2020 16:24:28
User entered '15 Aug 2020 12:24'	System	15 Aug 2020 16:24:28

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 6'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:25', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'c4ec6fbd-df3d-4440-8551-238eab6e3603'	System	17 Aug 2020 11:05:40
User entered 'None (1)'	System	17 Aug 2020 11:05:40

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:28', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'c4ec6fbd-df3d-4440-8551-238eab6e3603'	System	17 Aug 2020 11:05:40
User entered 'No (N)'	System	17 Aug 2020 11:05:40

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:30', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'c4ec6fbd-df3d-4440-8551-238eab6e3603'	System	17 Aug 2020 11:05:40
User entered 'No (N)'	System	17 Aug 2020 11:05:40

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:33', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'c4ec6fbd-df3d-4440-8551-238eab6e3603'	System	17 Aug 2020 11:05:40
User entered 'None (1)'	System	17 Aug 2020 11:05:40

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:35', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'c4ec6fbd-df3d-4440-8551-238eab6e3603'	System	17 Aug 2020 11:05:40
User entered '17 Aug 2020 07:05'	System	17 Aug 2020 11:05:40

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 7'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:13', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '94a7cb8e-be03-4a8d-a2ca-ddc7e6d108c1'	System	18 Aug 2020 00:39:23
User entered 'None (1)'	System	18 Aug 2020 00:39:23

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:15', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '94a7cb8e-be03-4a8d-a2ca-ddc7e6d108c1'	System	18 Aug 2020 00:39:23
User entered 'No (N)'	System	18 Aug 2020 00:39:23

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:17', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '94a7cb8e-be03-4a8d-a2ca-ddc7e6d108c1'	System	18 Aug 2020 00:39:23
User entered 'No (N)'	System	18 Aug 2020 00:39:23

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:19', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '94a7cb8e-be03-4a8d-a2ca-ddc7e6d108c1'	System	18 Aug 2020 00:39:23
User entered 'None (1)'	System	18 Aug 2020 00:39:23

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:21', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '94a7cb8e-be03-4a8d-a2ca-ddc7e6d108c1'	System	18 Aug 2020 00:39:23
User entered '17 Aug 2020 20:39'	System	18 Aug 2020 00:39:23

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:18:21', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '5192ab14-17ed-42bd-a4c5-b8531d79bed7'	System	11 Aug 2020 21:03:38
User entered 'None (0)'	System	11 Aug 2020 21:03:38

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:18:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '5192ab14-17ed-42bd-a4c5-b8531d79bed7'	System	11 Aug 2020 21:03:38
User entered 'None (0)'	System	11 Aug 2020 21:03:38

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:18:27', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '5192ab14-17ed-42bd-a4c5-b8531d79bed7'	System	11 Aug 2020 21:03:38
User entered 'None (0)'	System	11 Aug 2020 21:03:38

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:18:30', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '5192ab14-17ed-42bd-a4c5-b8531d79bed7'	System	11 Aug 2020 21:03:38
User entered 'None (0)'	System	11 Aug 2020 21:03:38

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:18:32', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '5192ab14-17ed-42bd-a4c5-b8531d79bed7'	System	11 Aug 2020 21:03:38
User entered 'None (0)'	System	11 Aug 2020 21:03:38

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:18:34', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '5192ab14-17ed-42bd-a4c5-b8531d79bed7'	System	11 Aug 2020 21:03:38
User entered 'None (0)'	System	11 Aug 2020 21:03:38

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:18:37', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '5192ab14-17ed-42bd-a4c5-b8531d79bed7'	System	11 Aug 2020 21:03:38
User entered 'No (N)'	System	11 Aug 2020 21:03:38

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T11:18:39', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '5192ab14-17ed-42bd-a4c5-b8531d79bed7'	System	11 Aug 2020 21:03:38
User entered '11 Aug 2020 11:18'	System	11 Aug 2020 21:03:38

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:05'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 13:35'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:40', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '631850da-7caa-4b01-b3e0-95876949fb51'	System	11 Aug 2020 21:04:59
User entered 'None (0)'	System	11 Aug 2020 21:04:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:42', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '631850da-7caa-4b01-b3e0-95876949fb51'	System	11 Aug 2020 21:04:59
User entered 'None (0)'	System	11 Aug 2020 21:04:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:45', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '631850da-7caa-4b01-b3e0-95876949fb51'	System	11 Aug 2020 21:04:59
User entered 'None (0)'	System	11 Aug 2020 21:04:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:47', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '631850da-7caa-4b01-b3e0-95876949fb51'	System	11 Aug 2020 21:04:59
User entered 'None (0)'	System	11 Aug 2020 21:04:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:49', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '631850da-7caa-4b01-b3e0-95876949fb51'	System	11 Aug 2020 21:04:59
User entered 'None (0)'	System	11 Aug 2020 21:04:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:51', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '631850da-7caa-4b01-b3e0-95876949fb51'	System	11 Aug 2020 21:04:59
User entered 'None (0)'	System	11 Aug 2020 21:04:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:54', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '631850da-7caa-4b01-b3e0-95876949fb51'	System	11 Aug 2020 21:04:59
User entered 'No (N)'	System	11 Aug 2020 21:04:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-11T17:04:56', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '631850da-7caa-4b01-b3e0-95876949fb51'	System	11 Aug 2020 21:04:59
User entered '11 Aug 2020 17:04'	System	11 Aug 2020 21:04:59

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 14:30'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 2'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:07', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0741eec-6438-4b3f-b6aa-ae11c7259d85'	System	12 Aug 2020 18:27:27
User entered 'None (0)'	System	12 Aug 2020 18:27:27

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:09', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0741eec-6438-4b3f-b6aa-ae11c7259d85'	System	12 Aug 2020 18:27:27
User entered 'None (0)'	System	12 Aug 2020 18:27:27

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:10', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0741eec-6438-4b3f-b6aa-ae11c7259d85'	System	12 Aug 2020 18:27:27
User entered 'None (0)'	System	12 Aug 2020 18:27:27

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:12', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0741eec-6438-4b3f-b6aa-ae11c7259d85'	System	12 Aug 2020 18:27:27
User entered 'None (0)'	System	12 Aug 2020 18:27:27

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:14', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0741eec-6438-4b3f-b6aa-ae11c7259d85'	System	12 Aug 2020 18:27:27
User entered 'None (0)'	System	12 Aug 2020 18:27:27

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:16', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0741eec-6438-4b3f-b6aa-ae11c7259d85'	System	12 Aug 2020 18:27:27
User entered 'None (0)'	System	12 Aug 2020 18:27:27

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:21', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0741eec-6438-4b3f-b6aa-ae11c7259d85'	System	12 Aug 2020 18:27:27
User entered 'No (N)'	System	12 Aug 2020 18:27:27

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-12T14:27:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0741eec-6438-4b3f-b6aa-ae11c7259d85'	System	12 Aug 2020 18:27:27
User entered '12 Aug 2020 14:27'	System	12 Aug 2020 18:27:27

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 3'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:08', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '453af2c3-f7fb-40d8-9f41-99e560b720f9'	System	13 Aug 2020 16:01:26
User entered 'None (0)'	System	13 Aug 2020 16:01:26

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:09', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '453af2c3-f7fb-40d8-9f41-99e560b720f9'	System	13 Aug 2020 16:01:26
User entered 'None (0)'	System	13 Aug 2020 16:01:26

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:11', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '453af2c3-f7fb-40d8-9f41-99e560b720f9'	System	13 Aug 2020 16:01:26
User entered 'None (0)'	System	13 Aug 2020 16:01:26

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:12', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '453af2c3-f7fb-40d8-9f41-99e560b720f9'	System	13 Aug 2020 16:01:26
User entered 'None (0)'	System	13 Aug 2020 16:01:26

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:14', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '453af2c3-f7fb-40d8-9f41-99e560b720f9'	System	13 Aug 2020 16:01:26
User entered 'None (0)'	System	13 Aug 2020 16:01:26

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:15', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '453af2c3-f7fb-40d8-9f41-99e560b720f9'	System	13 Aug 2020 16:01:26
User entered 'None (0)'	System	13 Aug 2020 16:01:26

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:18', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '453af2c3-f7fb-40d8-9f41-99e560b720f9'	System	13 Aug 2020 16:01:26
User entered 'No (N)'	System	13 Aug 2020 16:01:26

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-13T12:01:20', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '453af2c3-f7fb-40d8-9f41-99e560b720f9'	System	13 Aug 2020 16:01:26
User entered '13 Aug 2020 12:01'	System	13 Aug 2020 16:01:26

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 4'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:50', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'af1be0e5-056c-4ded-b9df-ac8b5402626f'	System	15 Aug 2020 04:00:08
User entered 'None (0)'	System	15 Aug 2020 04:00:08

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:52', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'af1be0e5-056c-4ded-b9df-ac8b5402626f' User entered 'None (0)'	System	15 Aug 2020 04:00:08
	System	15 Aug 2020 04:00:08

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:53', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'af1be0e5-056c-4ded-b9df-ac8b5402626f'	System	15 Aug 2020 04:00:08
User entered 'None (0)'	System	15 Aug 2020 04:00:08

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:54', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'af1be0e5-056c-4ded-b9df-ac8b5402626f'	System	15 Aug 2020 04:00:08
User entered 'None (0)'	System	15 Aug 2020 04:00:08

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:57', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'af1be0e5-056c-4ded-b9df-ac8b5402626f' User entered 'None (0)'	System	15 Aug 2020 04:00:08
	System	15 Aug 2020 04:00:08

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-14T23:59:59', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'af1be0e5-056c-4ded-b9df-ac8b5402626f' User entered 'None (0)'	System	15 Aug 2020 04:00:08
	System	15 Aug 2020 04:00:08

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T00:00:01', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'af1be0e5-056c-4ded-b9df-ac8b5402626f'	System	15 Aug 2020 04:00:08
User entered 'No (N)'	System	15 Aug 2020 04:00:08

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T00:00:03', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'af1be0e5-056c-4ded-b9df-ac8b5402626f' User entered '15 Aug 2020 00:00'	System	15 Aug 2020 04:00:08
	System	15 Aug 2020 04:00:08

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 5'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:29', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8fef228f-7084-41e4-9a3c-f3b8b828935f'	System	15 Aug 2020 16:24:45
User entered 'None (0)'	System	15 Aug 2020 16:24:45

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:32', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8fef228f-7084-41e4-9a3c-f3b8b828935f'	System	15 Aug 2020 16:24:45
User entered 'None (0)'	System	15 Aug 2020 16:24:45

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:33', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8fef228f-7084-41e4-9a3c-f3b8b828935f'	System	15 Aug 2020 16:24:45
User entered 'None (0)'	System	15 Aug 2020 16:24:45

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:35', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8fef228f-7084-41e4-9a3c-f3b8b828935f'	System	15 Aug 2020 16:24:45
User entered 'None (0)'	System	15 Aug 2020 16:24:45

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:37', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8fef228f-7084-41e4-9a3c-f3b8b828935f'	System	15 Aug 2020 16:24:45
User entered 'None (0)'	System	15 Aug 2020 16:24:45

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:38', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8fef228f-7084-41e4-9a3c-f3b8b828935f'	System	15 Aug 2020 16:24:45
User entered 'None (0)'	System	15 Aug 2020 16:24:45

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:42', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8fef228f-7084-41e4-9a3c-f3b8b828935f'	System	15 Aug 2020 16:24:45
User entered 'No (N)'	System	15 Aug 2020 16:24:45

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-15T12:24:44', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8fef228f-7084-41e4-9a3c-f3b8b828935f'	System	15 Aug 2020 16:24:45
User entered '15 Aug 2020 12:24'	System	15 Aug 2020 16:24:45

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 6'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:38', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '54fee72d-d0f2-4e0f-9a7f-c2c7606de551'	System	17 Aug 2020 11:05:53
User entered 'None (0)'	System	17 Aug 2020 11:05:53

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:40', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '54fee72d-d0f2-4e0f-9a7f-c2c7606de551'	System	17 Aug 2020 11:05:53
User entered 'None (0)'	System	17 Aug 2020 11:05:53

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:42', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '54fee72d-d0f2-4e0f-9a7f-c2c7606de551'	System	17 Aug 2020 11:05:53
User entered 'None (0)'	System	17 Aug 2020 11:05:53

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:43', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '54fee72d-d0f2-4e0f-9a7f-c2c7606de551'	System	17 Aug 2020 11:05:53
User entered 'None (0)'	System	17 Aug 2020 11:05:53

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:45', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '54fee72d-d0f2-4e0f-9a7f-c2c7606de551'	System	17 Aug 2020 11:05:53
User entered 'None (0)'	System	17 Aug 2020 11:05:53

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:47', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '54fee72d-d0f2-4e0f-9a7f-c2c7606de551'	System	17 Aug 2020 11:05:53
User entered 'None (0)'	System	17 Aug 2020 11:05:53

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:50', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '54fee72d-d0f2-4e0f-9a7f-c2c7606de551'	System	17 Aug 2020 11:05:53
User entered 'No (N)'	System	17 Aug 2020 11:05:53

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T07:05:51', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '54fee72d-d0f2-4e0f-9a7f-c2c7606de551'	System	17 Aug 2020 11:05:53
User entered '17 Aug 2020 07:05'	System	17 Aug 2020 11:05:53

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 7'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '1b79e725-7e1c-4cd8-a7bb-a247bc719f2e'	System	18 Aug 2020 00:39:41
User entered 'None (0)'	System	18 Aug 2020 00:39:41

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:26', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '1b79e725-7e1c-4cd8-a7bb-a247bc719f2e'	System	18 Aug 2020 00:39:41
User entered 'None (0)'	System	18 Aug 2020 00:39:41

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:27', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '1b79e725-7e1c-4cd8-a7bb-a247bc719f2e'	System	18 Aug 2020 00:39:41
User entered 'None (0)'	System	18 Aug 2020 00:39:41

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:29', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '1b79e725-7e1c-4cd8-a7bb-a247bc719f2e'	System	18 Aug 2020 00:39:41
User entered 'None (0)'	System	18 Aug 2020 00:39:41

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:30', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '1b79e725-7e1c-4cd8-a7bb-a247bc719f2e'	System	18 Aug 2020 00:39:41
User entered 'None (0)'	System	18 Aug 2020 00:39:41

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:32', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '1b79e725-7e1c-4cd8-a7bb-a247bc719f2e'	System	18 Aug 2020 00:39:41
User entered 'None (0)'	System	18 Aug 2020 00:39:41

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:36', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '1b79e725-7e1c-4cd8-a7bb-a247bc719f2e'	System	18 Aug 2020 00:39:41
User entered 'No (N)'	System	18 Aug 2020 00:39:41

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-08-17T20:39:37', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '1b79e725-7e1c-4cd8-a7bb-a247bc719f2e'	System	18 Aug 2020 00:39:41
User entered '17 Aug 2020 20:39'	System	18 Aug 2020 00:39:41

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 14:49:15

US3522077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 13:16:17

US3522077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 13:16:17

US3522077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	18 Aug 2020 13:16:17

US3522077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' answered with '1 attempt 1 day' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	29 Sep 2020 20:32:25
User opened query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	23 Sep 2020 21:15:58
User entered 'Called but pt. did not answer the phone'	(b) (4), (b) (6) (b) (4)	18 Aug 2020 13:16:17

US3522077

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	25 Aug 2020 13:23:13

US3522077

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 13:23:13

US3522077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Aug 2020 13:25:32
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Aug 2020 13:23:50
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	25 Aug 2020 13:23:50

US3522077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Kristin Eis (b) (4) (b) (4)	25 Aug 2020 13:23:50

US3522077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Kristin Eis (b) (4)	25 Aug 2020 13:25:32
User entered empty.	Kristin Eis (b) (4)	25 Aug 2020 13:23:50

US3522077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User closed query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:51:37
Query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' answered with '2 attempts over one day' (Site from CRA).	Sharon Mathys (b) (4)	29 Sep 2020 20:30:44
User opened query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 21:16:11
User entered 'patient did not answer; voicemail was left- will call again later today' reason for change: Data Entry Error	Kristin Eis (b) (4)	25 Aug 2020 13:25:32
User entered empty.	Kristin Eis (b) (4)	25 Aug 2020 13:23:50

US3522077

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	25 Aug 2020 13:23:54

US3522077

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 13:23:54

US3522077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 14:53:30

US3522077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 14:53:30

US3522077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 14:53:30

US3522077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure risk'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 14:53:30

US3522077

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 14:53:36

US3522077

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 14:53:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:35:38

US3522077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 16:35:38

US3522077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Sep 2020 16:35:38

US3522077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Sep 2020 16:35:38

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '12:32'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:32'	System	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '97.3' F reason for change: Data Entry Error	Kristin Eis (b) (4)	30 Sep 2020 19:50:37
User entered '97' F	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '97'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '141'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '88'	(b) (4), (b) (6)	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 16:36:36

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '13:25'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:25'	System	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6) [REDACTED]	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'TEMPORAL'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '97'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '127'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 17:39:26

US3522077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:36:52

US3522077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 16:36:52

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6) [REDACTED]	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '12:55'	(b) (4), (b) (6)	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 17:00:19

US3522077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:00:51

US3522077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:00:51

US3522077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:50'	(b) (4), (b) (6)	10 Sep 2020 17:00:51

US3522077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:50'	System	10 Sep 2020 17:00:51

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:41

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '12:52'	(b) (4), (b) (6)	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:52'	System	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:41

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:41

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6) [REDACTED]	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:01:04

US3522077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 16:37:01

US3522077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 16:37:01

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:16:31', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '19080826-d569-4df7-8e12-d08ba44fb9e2'	System	10 Sep 2020 17:16:55
User entered 'Yes (Y)'	System	10 Sep 2020 17:16:55

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:16:43', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '19080826-d569-4df7-8e12-d08ba44fb9e2'	System	10 Sep 2020 17:16:55
User entered '98.0'	System	10 Sep 2020 17:16:55

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:16:47', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '19080826-d569-4df7-8e12-d08ba44fb9e2'	System	10 Sep 2020 17:16:55
User entered 'No (N)'	System	10 Sep 2020 17:16:55

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:16:51', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '19080826-d569-4df7-8e12-d08ba44fb9e2'	System	10 Sep 2020 17:16:55
User entered '10 Sep 2020 13:16'	System	10 Sep 2020 17:16:55

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:15'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:41:43', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '76b26de9-cc1b-49e8-a42e-0beaa8dcde9a'	System	10 Sep 2020 23:41:59
User entered 'Yes (Y)'	System	10 Sep 2020 23:41:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:41:49', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '76b26de9-cc1b-49e8-a42e-0beaa8dcde9a' User entered '97.8'	System	10 Sep 2020 23:41:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:41:53', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '76b26de9-cc1b-49e8-a42e-0beaa8dcde9a'	System	10 Sep 2020 23:41:59
User entered 'No (N)'	System	10 Sep 2020 23:41:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:41:56', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '76b26de9-cc1b-49e8-a42e-0beaa8dcde9a' User entered '10 Sep 2020 19:41'	System	10 Sep 2020 23:41:59
	System	10 Sep 2020 23:41:59

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:40'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 2'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:13', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef3ca370-1732-462d-b36f-15460b52c4d7'	System	11 Sep 2020 19:25:23
User entered 'Yes (Y)'	System	11 Sep 2020 19:25:23

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:16', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef3ca370-1732-462d-b36f-15460b52c4d7'	System	11 Sep 2020 19:25:23
User entered '98.0'	System	11 Sep 2020 19:25:23

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:19', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef3ca370-1732-462d-b36f-15460b52c4d7'	System	11 Sep 2020 19:25:23
User entered 'No (N)'	System	11 Sep 2020 19:25:23

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:20', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef3ca370-1732-462d-b36f-15460b52c4d7'	System	11 Sep 2020 19:25:23
User entered '11 Sep 2020 15:25'	System	11 Sep 2020 19:25:23

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 3'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:19', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '015199a4-1984-4053-b3ba-f7eb822d5fc5'	System	13 Sep 2020 03:59:26
User entered 'No (N)'	System	13 Sep 2020 03:59:26

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:21', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '015199a4-1984-4053-b3ba-f7eb822d5fc5'	System	13 Sep 2020 03:59:26
User entered 'No (N)'	System	13 Sep 2020 03:59:26

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '015199a4-1984-4053-b3ba-f7eb822d5fc5'	System	13 Sep 2020 03:59:26
User entered '12 Sep 2020 23:59'	System	13 Sep 2020 03:59:26

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 4'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 5'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:19:57', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0cffc4b6-411d-4dc5-bb2d-4bb28f98ced9'	System	15 Sep 2020 11:20:10
User entered 'Yes (Y)'	System	15 Sep 2020 11:20:10

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:01', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0cffc4b6-411d-4dc5-bb2d-4bb28f98ced9'	System	15 Sep 2020 11:20:10
User entered '98.0'	System	15 Sep 2020 11:20:10

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:04', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0cffc4b6-411d-4dc5-bb2d-4bb28f98ced9'	System	15 Sep 2020 11:20:10
User entered 'No (N)'	System	15 Sep 2020 11:20:10

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:06', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0cffc4b6-411d-4dc5-bb2d-4bb28f98ced9' User entered '15 Sep 2020 07:20'	System	15 Sep 2020 11:20:10
	System	15 Sep 2020 11:20:10

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 6'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:02', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cb3dfebb-ae55-4054-bf07-9c0574502334'	System	16 Sep 2020 10:43:12
User entered 'No (N)'	System	16 Sep 2020 10:43:12

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:04', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cb3dfebb-ae55-4054-bf07-9c0574502334'	System	16 Sep 2020 10:43:12
User entered 'No (N)'	System	16 Sep 2020 10:43:12

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:07', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cb3dfebb-ae55-4054-bf07-9c0574502334'	System	16 Sep 2020 10:43:12
User entered '16 Sep 2020 06:43'	System	16 Sep 2020 10:43:12

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 7'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:50:54', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '75a2b01a-372f-4531-896e-a0eacf8f4a8f' User entered 'Yes (Y)'	System	17 Sep 2020 10:51:09

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:02', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '75a2b01a-372f-4531-896e-a0eacf8f4a8f' User entered '98.0'	System	17 Sep 2020 10:51:09

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:04', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '75a2b01a-372f-4531-896e-a0eacf8f4a8f'	System	17 Sep 2020 10:51:09
User entered 'No (N)'	System	17 Sep 2020 10:51:09

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:06', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '75a2b01a-372f-4531-896e-a0eacf8f4a8f' User entered '17 Sep 2020 06:51'	System	17 Sep 2020 10:51:09
	System	17 Sep 2020 10:51:09

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:16:55', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0dc32d06-447a-49cb-af0c-cf8fea0000df' User entered 'None (1)'	System	10 Sep 2020 17:17:08
	System	10 Sep 2020 17:17:08

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:16:58', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0dc32d06-447a-49cb-af0c-cf8fea0000df' User entered 'No (N)'	System	10 Sep 2020 17:17:08

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:00', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0dc32d06-447a-49cb-af0c-cf8fea0000df' User entered 'No (N)'	System	10 Sep 2020 17:17:08

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:02', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0dc32d06-447a-49cb-af0c-cf8fea0000df' User entered 'None (1)'	System	10 Sep 2020 17:17:08
	System	10 Sep 2020 17:17:08

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:05', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '0dc32d06-447a-49cb-af0c-cf8fea0000df' User entered '10 Sep 2020 13:17'	System	10 Sep 2020 17:17:08
	System	10 Sep 2020 17:17:08

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:15'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:00', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '824c2c5a-078c-45df-9e30-a954902a96f2'	System	10 Sep 2020 23:42:13
User entered 'None (1)'	System	10 Sep 2020 23:42:13

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:02', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '824c2c5a-078c-45df-9e30-a954902a96f2'	System	10 Sep 2020 23:42:13
User entered 'No (N)'	System	10 Sep 2020 23:42:13

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:03', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '824c2c5a-078c-45df-9e30-a954902a96f2'	System	10 Sep 2020 23:42:13
User entered 'No (N)'	System	10 Sep 2020 23:42:13

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:05', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '824c2c5a-078c-45df-9e30-a954902a96f2'	System	10 Sep 2020 23:42:13
User entered 'None (1)'	System	10 Sep 2020 23:42:13

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:07', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '824c2c5a-078c-45df-9e30-a954902a96f2'	System	10 Sep 2020 23:42:13
User entered '10 Sep 2020 19:42'	System	10 Sep 2020 23:42:13

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:40'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 2'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8168c015-ec7d-46f4-803c-ec304c960601'	System	11 Sep 2020 19:25:35
User entered 'None (1)'	System	11 Sep 2020 19:25:35

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:26', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8168c015-ec7d-46f4-803c-ec304c960601'	System	11 Sep 2020 19:25:35
User entered 'No (N)'	System	11 Sep 2020 19:25:35

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:27', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8168c015-ec7d-46f4-803c-ec304c960601'	System	11 Sep 2020 19:25:35
User entered 'No (N)'	System	11 Sep 2020 19:25:35

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:29', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8168c015-ec7d-46f4-803c-ec304c960601'	System	11 Sep 2020 19:25:35
User entered 'None (1)'	System	11 Sep 2020 19:25:35

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:31', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8168c015-ec7d-46f4-803c-ec304c960601'	System	11 Sep 2020 19:25:35
User entered '11 Sep 2020 15:25'	System	11 Sep 2020 19:25:35

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 3'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:28', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '90706f39-829e-46c8-a990-288544d6c09f'	System	13 Sep 2020 03:59:40
User entered 'None (1)'	System	13 Sep 2020 03:59:40

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:31', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '90706f39-829e-46c8-a990-288544d6c09f'	System	13 Sep 2020 03:59:40
User entered 'No (N)'	System	13 Sep 2020 03:59:40

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:32', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '90706f39-829e-46c8-a990-288544d6c09f'	System	13 Sep 2020 03:59:40
User entered 'No (N)'	System	13 Sep 2020 03:59:40

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:35', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '90706f39-829e-46c8-a990-288544d6c09f' User entered 'None (1)'	System	13 Sep 2020 03:59:40
	System	13 Sep 2020 03:59:40

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:36', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '90706f39-829e-46c8-a990-288544d6c09f'	System	13 Sep 2020 03:59:40
User entered '12 Sep 2020 23:59'	System	13 Sep 2020 03:59:40

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 4'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 5'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:09', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '62f58fb6-6c76-45a0-85cf-c7569627d939'	System	15 Sep 2020 11:20:18
User entered 'None (1)'	System	15 Sep 2020 11:20:18

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:11', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '62f58fb6-6c76-45a0-85cf-c7569627d939'	System	15 Sep 2020 11:20:18
User entered 'No (N)'	System	15 Sep 2020 11:20:18

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:13', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '62f58fb6-6c76-45a0-85cf-c7569627d939'	System	15 Sep 2020 11:20:18
User entered 'No (N)'	System	15 Sep 2020 11:20:18

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:15', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '62f58fb6-6c76-45a0-85cf-c7569627d939'	System	15 Sep 2020 11:20:18
User entered 'None (1)'	System	15 Sep 2020 11:20:18

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:16', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '62f58fb6-6c76-45a0-85cf-c7569627d939'	System	15 Sep 2020 11:20:18
User entered '15 Sep 2020 07:20'	System	15 Sep 2020 11:20:18

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 6'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:11', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8972efe1-387c-45f1-bd7b-692873fdd811'	System	16 Sep 2020 10:43:21
User entered 'None (1)'	System	16 Sep 2020 10:43:21

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:13', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8972efe1-387c-45f1-bd7b-692873fdd811'	System	16 Sep 2020 10:43:21
User entered 'No (N)'	System	16 Sep 2020 10:43:21

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:14', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8972efe1-387c-45f1-bd7b-692873fdd811'	System	16 Sep 2020 10:43:21
User entered 'No (N)'	System	16 Sep 2020 10:43:21

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:16', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8972efe1-387c-45f1-bd7b-692873fdd811'	System	16 Sep 2020 10:43:21
User entered 'None (1)'	System	16 Sep 2020 10:43:21

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:18', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '8972efe1-387c-45f1-bd7b-692873fdd811'	System	16 Sep 2020 10:43:21
User entered '16 Sep 2020 06:43'	System	16 Sep 2020 10:43:21

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 7'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:10', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '35cb8bce-d9c2-402f-82af-b839c5fdbe8a'	System	17 Sep 2020 10:51:20
User entered 'None (1)'	System	17 Sep 2020 10:51:20

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:12', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '35cb8bce-d9c2-402f-82af-b839c5fdbe8a'	System	17 Sep 2020 10:51:20
User entered 'No (N)'	System	17 Sep 2020 10:51:20

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:13', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '35cb8bce-d9c2-402f-82af-b839c5fdbe8a'	System	17 Sep 2020 10:51:20
User entered 'No (N)'	System	17 Sep 2020 10:51:20

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:15', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '35cb8bce-d9c2-402f-82af-b839c5fdbe8a' User entered 'None (1)'	System	17 Sep 2020 10:51:20
	System	17 Sep 2020 10:51:20

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:17', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '35cb8bce-d9c2-402f-82af-b839c5fdbe8a' User entered '17 Sep 2020 06:51'	System	17 Sep 2020 10:51:20
	System	17 Sep 2020 10:51:20

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:08', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '903d8010-d2aa-4bdf-baa3-d5cc75c9a2f5'	System	10 Sep 2020 17:17:25
User entered 'None (0)'	System	10 Sep 2020 17:17:25

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:10', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '903d8010-d2aa-4bdf-baa3-d5cc75c9a2f5'	System	10 Sep 2020 17:17:25
User entered 'None (0)'	System	10 Sep 2020 17:17:25

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:12', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '903d8010-d2aa-4bdf-baa3-d5cc75c9a2f5'	System	10 Sep 2020 17:17:25
User entered 'None (0)'	System	10 Sep 2020 17:17:25

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:13', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '903d8010-d2aa-4bdf-baa3-d5cc75c9a2f5'	System	10 Sep 2020 17:17:25
User entered 'None (0)'	System	10 Sep 2020 17:17:25

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:16', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '903d8010-d2aa-4bdf-baa3-d5cc75c9a2f5'	System	10 Sep 2020 17:17:25
User entered 'None (0)'	System	10 Sep 2020 17:17:25

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:18', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '903d8010-d2aa-4bdf-baa3-d5cc75c9a2f5'	System	10 Sep 2020 17:17:25
User entered 'None (0)'	System	10 Sep 2020 17:17:25

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:21', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '903d8010-d2aa-4bdf-baa3-d5cc75c9a2f5'	System	10 Sep 2020 17:17:25
User entered 'No (N)'	System	10 Sep 2020 17:17:25

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T13:17:23', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '903d8010-d2aa-4bdf-baa3-d5cc75c9a2f5'	System	10 Sep 2020 17:17:25
User entered '10 Sep 2020 13:17'	System	10 Sep 2020 17:17:25

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:15'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:10', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '40c7fc52-c914-4530-98e3-b6b6ca146419'	System	10 Sep 2020 23:42:27
User entered 'None (0)'	System	10 Sep 2020 23:42:27

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:12', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '40c7fc52-c914-4530-98e3-b6b6ca146419'	System	10 Sep 2020 23:42:27
User entered 'None (0)'	System	10 Sep 2020 23:42:27

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:14', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '40c7fc52-c914-4530-98e3-b6b6ca146419'	System	10 Sep 2020 23:42:27
User entered 'None (0)'	System	10 Sep 2020 23:42:27

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:16', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '40c7fc52-c914-4530-98e3-b6b6ca146419'	System	10 Sep 2020 23:42:27
User entered 'None (0)'	System	10 Sep 2020 23:42:27

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:17', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '40c7fc52-c914-4530-98e3-b6b6ca146419'	System	10 Sep 2020 23:42:27
User entered 'None (0)'	System	10 Sep 2020 23:42:27

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:19', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '40c7fc52-c914-4530-98e3-b6b6ca146419'	System	10 Sep 2020 23:42:27
User entered 'None (0)'	System	10 Sep 2020 23:42:27

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:22', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '40c7fc52-c914-4530-98e3-b6b6ca146419'	System	10 Sep 2020 23:42:27
User entered 'No (N)'	System	10 Sep 2020 23:42:27

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-10T19:42:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '40c7fc52-c914-4530-98e3-b6b6ca146419'	System	10 Sep 2020 23:42:27
User entered '10 Sep 2020 19:42'	System	10 Sep 2020 23:42:27

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:40'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 2'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:34', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'fc3ccbfc-3ac1-45bd-82e4-629be53fa635'	System	11 Sep 2020 19:25:54
User entered 'None (0)'	System	11 Sep 2020 19:25:54

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:36', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'fc3ccbfc-3ac1-45bd-82e4-629be53fa635'	System	11 Sep 2020 19:25:54
User entered 'None (0)'	System	11 Sep 2020 19:25:54

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:38', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'fc3ccbfc-3ac1-45bd-82e4-629be53fa635'	System	11 Sep 2020 19:25:54
User entered 'None (0)'	System	11 Sep 2020 19:25:54

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:40', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'fc3ccbfc-3ac1-45bd-82e4-629be53fa635'	System	11 Sep 2020 19:25:54
User entered 'None (0)'	System	11 Sep 2020 19:25:54

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:42', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'fc3ccbfc-3ac1-45bd-82e4-629be53fa635'	System	11 Sep 2020 19:25:54
User entered 'None (0)'	System	11 Sep 2020 19:25:54

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:44', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'fc3ccbfc-3ac1-45bd-82e4-629be53fa635'	System	11 Sep 2020 19:25:54
User entered 'None (0)'	System	11 Sep 2020 19:25:54

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:48', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'fc3ccbfc-3ac1-45bd-82e4-629be53fa635'	System	11 Sep 2020 19:25:54
User entered 'No (N)'	System	11 Sep 2020 19:25:54

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-11T15:25:50', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'fc3ccbfc-3ac1-45bd-82e4-629be53fa635'	System	11 Sep 2020 19:25:54
User entered '11 Sep 2020 15:25'	System	11 Sep 2020 19:25:54

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 3'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:39', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef30254c-b3ac-4be2-9d1e-f2c363a917df'	System	13 Sep 2020 03:59:56
User entered 'None (0)'	System	13 Sep 2020 03:59:56

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:41', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef30254c-b3ac-4be2-9d1e-f2c363a917df'	System	13 Sep 2020 03:59:56
User entered 'None (0)'	System	13 Sep 2020 03:59:56

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:43', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef30254c-b3ac-4be2-9d1e-f2c363a917df'	System	13 Sep 2020 03:59:56
User entered 'None (0)'	System	13 Sep 2020 03:59:56

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:45', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef30254c-b3ac-4be2-9d1e-f2c363a917df'	System	13 Sep 2020 03:59:56
User entered 'None (0)'	System	13 Sep 2020 03:59:56

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:46', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef30254c-b3ac-4be2-9d1e-f2c363a917df'	System	13 Sep 2020 03:59:56
User entered 'None (0)'	System	13 Sep 2020 03:59:56

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:48', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef30254c-b3ac-4be2-9d1e-f2c363a917df'	System	13 Sep 2020 03:59:56
User entered 'None (0)'	System	13 Sep 2020 03:59:56

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:51', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef30254c-b3ac-4be2-9d1e-f2c363a917df'	System	13 Sep 2020 03:59:56
User entered 'No (N)'	System	13 Sep 2020 03:59:56

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-12T23:59:53', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'ef30254c-b3ac-4be2-9d1e-f2c363a917df'	System	13 Sep 2020 03:59:56
User entered '12 Sep 2020 23:59'	System	13 Sep 2020 03:59:56

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 4'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 5'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:19', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'e1afc1d2-3ad6-4529-af99-08223609074c'	System	15 Sep 2020 11:20:34
User entered 'None (0)'	System	15 Sep 2020 11:20:34

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:21', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'e1afc1d2-3ad6-4529-af99-08223609074c'	System	15 Sep 2020 11:20:34
User entered 'None (0)'	System	15 Sep 2020 11:20:34

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:22', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'e1afc1d2-3ad6-4529-af99-08223609074c'	System	15 Sep 2020 11:20:34
User entered 'None (0)'	System	15 Sep 2020 11:20:34

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'e1afc1d2-3ad6-4529-af99-08223609074c'	System	15 Sep 2020 11:20:34
User entered 'None (0)'	System	15 Sep 2020 11:20:34

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:25', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'e1afc1d2-3ad6-4529-af99-08223609074c'	System	15 Sep 2020 11:20:34
User entered 'None (0)'	System	15 Sep 2020 11:20:34

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:27', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'e1afc1d2-3ad6-4529-af99-08223609074c'	System	15 Sep 2020 11:20:34
User entered 'None (0)'	System	15 Sep 2020 11:20:34

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:30', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'e1afc1d2-3ad6-4529-af99-08223609074c'	System	15 Sep 2020 11:20:34
User entered 'No (N)'	System	15 Sep 2020 11:20:34

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-15T07:20:31', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'e1afc1d2-3ad6-4529-af99-08223609074c' User entered '15 Sep 2020 07:20'	System	15 Sep 2020 11:20:34
	System	15 Sep 2020 11:20:34

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 6'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:22', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '22915d0c-ca85-4a2a-8e06-8a8b59926f02'	System	16 Sep 2020 10:43:36
User entered 'None (0)'	System	16 Sep 2020 10:43:36

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '22915d0c-ca85-4a2a-8e06-8a8b59926f02'	System	16 Sep 2020 10:43:36
User entered 'None (0)'	System	16 Sep 2020 10:43:36

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:25', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '22915d0c-ca85-4a2a-8e06-8a8b59926f02'	System	16 Sep 2020 10:43:36
User entered 'None (0)'	System	16 Sep 2020 10:43:36

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:27', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '22915d0c-ca85-4a2a-8e06-8a8b59926f02'	System	16 Sep 2020 10:43:36
User entered 'None (0)'	System	16 Sep 2020 10:43:36

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:29', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '22915d0c-ca85-4a2a-8e06-8a8b59926f02'	System	16 Sep 2020 10:43:36
User entered 'None (0)'	System	16 Sep 2020 10:43:36

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:31', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '22915d0c-ca85-4a2a-8e06-8a8b59926f02'	System	16 Sep 2020 10:43:36
User entered 'None (0)'	System	16 Sep 2020 10:43:36

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:33', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '22915d0c-ca85-4a2a-8e06-8a8b59926f02'	System	16 Sep 2020 10:43:36
User entered 'No (N)'	System	16 Sep 2020 10:43:36

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-16T06:43:34', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '22915d0c-ca85-4a2a-8e06-8a8b59926f02'	System	16 Sep 2020 10:43:36
User entered '16 Sep 2020 06:43'	System	16 Sep 2020 10:43:36

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:00:19
User entered 'Day 7'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:20', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cc105edc-b5c7-45cb-80b3-f09281966d14'	System	17 Sep 2020 10:51:37
User entered 'None (0)'	System	17 Sep 2020 10:51:37

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:22', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cc105edc-b5c7-45cb-80b3-f09281966d14'	System	17 Sep 2020 10:51:37
User entered 'None (0)'	System	17 Sep 2020 10:51:37

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:24', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cc105edc-b5c7-45cb-80b3-f09281966d14'	System	17 Sep 2020 10:51:37
User entered 'None (0)'	System	17 Sep 2020 10:51:37

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:26', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cc105edc-b5c7-45cb-80b3-f09281966d14'	System	17 Sep 2020 10:51:37
User entered 'None (0)'	System	17 Sep 2020 10:51:37

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:28', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cc105edc-b5c7-45cb-80b3-f09281966d14'	System	17 Sep 2020 10:51:37
User entered 'None (0)'	System	17 Sep 2020 10:51:37

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:30', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cc105edc-b5c7-45cb-80b3-f09281966d14'	System	17 Sep 2020 10:51:37
User entered 'None (0)'	System	17 Sep 2020 10:51:37

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:33', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cc105edc-b5c7-45cb-80b3-f09281966d14'	System	17 Sep 2020 10:51:37
User entered 'No (N)'	System	17 Sep 2020 10:51:37

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-09-17T06:51:35', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'cc105edc-b5c7-45cb-80b3-f09281966d14'	System	17 Sep 2020 10:51:37
User entered '17 Sep 2020 06:51'	System	17 Sep 2020 10:51:37

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 17:00:19

US3522077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:31:41

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 17:00:19

US3522077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:32:45

US3522077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 18:32:45

US3522077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	17 Sep 2020 18:32:45

US3522077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' answered with 'calling back 9/29' (Site from CRA).	Kristin Eis (b) (4) (b) (4)	29 Sep 2020 15:23:07
User opened query 'Remote visit query: Please verify how many attempts were made and how many days these attempts were made to contact subject. Per protocol there is a 3-day window for contacting subjects per each safety call.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 21:10:54
User entered 'voicemail left'	(b) (4), (b) (6)	17 Sep 2020 18:32:45

US3522077

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:50:54

US3522077

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:50:54

US3522077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:52:48

US3522077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 07:11:57
User entered '30 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4)	30 Sep 2020 21:01:38
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Kristin Eis (b) (4)	29 Sep 2020 15:24:22
answered with 'n/a' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Sep 2020 15:24:18
User entered '29 Sep 2020' reason for change: Data Entry Error	Kristin Eis (b) (4)	29 Sep 2020 15:24:18
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	24 Sep 2020 16:53:56
answered by data change (Site from System).		
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	24 Sep 2020 16:53:56
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:53:56
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	24 Sep 2020 16:52:48
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Sep 2020 16:52:48
User entered '24 Sep 2202'	(b) (4), (b) (6)	24 Sep 2020 16:52:48

US3522077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	24 Sep 2020 16:52:48

US3522077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered '1st attempt 24 Sep 2020, 2nd attempt 29 Sep 2020, 3rd attempt today' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	30 Sep 2020 21:01:38
User entered 'Left message'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 16:52:48

US3522077

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	01 Oct 2020 13:58:28

US3522077

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 13:58:28

US3522077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	01 Oct 2020 14:00:17

US3522077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 13:06:10
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'multiple contact attempts; see audit history' (Site from System).	Yaman Ahmed (b) (4)	08 Oct 2020 15:26:56
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	08 Oct 2020 15:26:45
User entered '8 Oct 2020' reason for change: New Information	Yaman Ahmed (b) (4)	08 Oct 2020 15:26:45
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 09:36:30
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Attempted to contact twice prior, third attempt today but no answer. ' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 13:38:58
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	06 Oct 2020 13:38:27
User entered '06 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	06 Oct 2020 13:38:27
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 13:21:53

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Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	05 Oct 2020 13:21:53
answered by data change (Site from System). User entered '02 Oct 2020' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 13:21:53
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 13:20:55
User entered '05 Oct 2020' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	05 Oct 2020 13:20:55
User entered '02 Oct 2020' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	02 Oct 2020 14:59:39
User entered '1 Oct 2020'	Alayna Wilder (b) (4) (b) (4)	01 Oct 2020 14:00:17

US3522077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	08 Oct 2020 15:26:45
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alayna Wilder (b) (4) (b) (4)	01 Oct 2020 14:00:17

US3522077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'E-DIARY FROM DAY 8 AND HE HAD NO AES AT THAT POINT. SINCE THEN, NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, OR COVID-19 EXPOSURE RISK' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	08 Oct 2020 15:26:34
User entered 'reviewed the e-diary from Day 8 and he had no AEs at that point in time. Since then, no ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, or Covid-19 exposure risk' (non-conformant).	Yaman Ahmed (b) (4) (b) (4)	08 Oct 2020 15:26:14
User entered '1st attempt 01-Oct-2020, 2nd attempt 02-Oct-2020, 3rd attempt today but no answer. Left a voicemail with call back number and email.' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	06 Oct 2020 13:38:20
User entered 'left vm'	Alayna Wilder (b) (4) (b) (4)	01 Oct 2020 14:00:17

US3522077

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	02 Oct 2020 14:59:41

US3522077

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 14:59:41

US3522077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 12:47:20

US3522077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 12:47:20

US3522077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 12:47:20

US3522077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:31:41

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Oct 2020 12:47:20

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '08:50'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 08:50'	System	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.2' F	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '87'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '139'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:31:41

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 13:00:12

US3522077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:00:32

US3522077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:31:41

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 13:00:32

US3522077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:00:46

US3522077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 13:00:46

US3522077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:56'	(b) (4), (b) (6)	12 Oct 2020 13:00:46

US3522077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 08:56'	System	12 Oct 2020 13:00:46

US3522077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:00:52

US3522077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 13:00:52

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 64'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-11T00:01:32', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '381b449d-ed45-42de-8f49-e4f7b39f8e10'	System	11 Oct 2020 04:01:42
User entered 'No (N)'	System	11 Oct 2020 04:01:42

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Have you been exposed to someone with 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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-11T00:01:35', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '381b449d-ed45-42de-8f49-e4f7b39f8e10'	System	11 Oct 2020 04:01:42
User entered 'No (N)'	System	11 Oct 2020 04:01:42

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-11T00:01:38', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '381b449d-ed45-42de-8f49-e4f7b39f8e10'	System	11 Oct 2020 04:01:42
User entered '11 Oct 2020 00:01:38'	System	11 Oct 2020 04:01:42

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 78'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-25T00:01:53', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'dd3f1a57-a58d-405d-8d51-fca5924eed3'	System	25 Oct 2020 04:02:34
User entered 'Yes (Y)'	System	25 Oct 2020 04:02:34

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Have you been exposed to someone with 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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-25T00:01:59', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'dd3f1a57-a58d-405d-8d51-fca5924eed3'	System	25 Oct 2020 04:02:34
User entered 'No (N)'	System	25 Oct 2020 04:02:34

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-25T00:02:03', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'dd3f1a57-a58d-405d-8d51-fca5924eed3'	System	25 Oct 2020 04:02:34
User entered 'No (N)'	System	25 Oct 2020 04:02:34

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-25T00:02:11', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'dd3f1a57-a58d-405d-8d51-fca5924eed3' User entered 'Yes (Y)'	System	25 Oct 2020 04:02:34

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-25T00:02:18', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'dd3f1a57-a58d-405d-8d51-fca5924eed3'	System	25 Oct 2020 04:02:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Oct 2020 04:02:34

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-10-25T00:02:22', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'dd3f1a57-a58d-405d-8d51-fca5924eed3' User entered '25 Oct 2020 00:02:22'	System	25 Oct 2020 04:02:34
	System	25 Oct 2020 04:02:34

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 92'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-11-11T18:29:57', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '6837ee21-fbb1-44d7-abfb-76ab97388d73' User entered 'No (N)'	System	11 Nov 2020 23:30:06
	System	11 Nov 2020 23:30:06

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Have you been exposed to someone with 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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-11-11T18:30:00', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '6837ee21-fbb1-44d7-abfb-76ab97388d73'	System	11 Nov 2020 23:30:06
User entered 'No (N)'	System	11 Nov 2020 23:30:06

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-11-11T18:30:03', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: '6837ee21-fbb1-44d7-abfb-76ab97388d73'	System	11 Nov 2020 23:30:06
User entered '11 Nov 2020 18:30:03'	System	11 Nov 2020 23:30:06

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered 'Day 99'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-11-15T03:33:06', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0e67b45-e999-491a-a475-673dad5fd982'	System	15 Nov 2020 08:33:13
User entered 'No (N)'	System	15 Nov 2020 08:33:13

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

Have you been exposed to someone with 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 (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-11-15T03:33:08', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0e67b45-e999-491a-a475-673dad5fd982'	System	15 Nov 2020 08:33:13
User entered 'No (N)'	System	15 Nov 2020 08:33:13

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9B45BFC3-69BF-480D-8F4D-74C0822D49D9)', Time: '2020-11-15T03:33:10', User OID: 'PatientReportedOutcome (US3522077)', ODM File OID: 'a0e67b45-e999-491a-a475-673dad5fd982'	System	15 Nov 2020 08:33:13
User entered '15 Nov 2020 03:33:10'	System	15 Nov 2020 08:33:13

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 14:49:15

US3522077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 14:49:15
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 14:49:15

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:32:24

US3522077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:31:41

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:32:24
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:32:24

US3522077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	05 Nov 2020 15:05:46

US3522077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered '6 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	06 Nov 2020 14:09:22
User entered '5 Nov 2020'	Yaman Ahmed (b) (4)	05 Nov 2020 15:05:46

US3522077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4), (b) (6)	06 Nov 2020 14:09:22
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	05 Nov 2020 15:05:46

US3522077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:31:41

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'" reason for change: New Information	(b) (4), (b) (6)	06 Nov 2020 14:09:22
User entered 'left a voicemail'	Yaman Ahmed (b) (4)	05 Nov 2020 15:05:46

US3522077

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 14:09:26

US3522077

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:31:41

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 14:09:26

US3522077

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:31:41

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per review of discharge source notes on 19Oct2020, lab shows slight BNP elevation, slight leukocytosis and slight normocytic anemia. Please advise if these meet the grade to be reported as an AE since these were labs as a result of MAAE. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 03:00:22
Query 'Per review of discharge source notes on 19Oct2020, lab shows slight BNP elevation, slight leukocytosis and slight normocytic anemia. Please advise if these meet the grade to be reported as an AE since these were labs as a result of MAAE. Thank you.' answered with 'see pulmonary embolism and normocytic anemia AE entries' (Site from CRA).	Yaman Ahmed (b) (4)	10 Nov 2020 20:09:27
User opened query 'Per review of discharge source notes on 19Oct2020, lab shows slight BNP elevation, slight leukocytosis and slight normocytic anemia. Please advise if these meet the grade to be reported as an AE since these were labs as a result of MAAE. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 18:04:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:02:40
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	27 Oct 2020 18:36:32

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:27
User entered 'USA-US131-2020-mRNA-1273-P301000009'	System	28 Oct 2020 17:55:23
User entered 'New'	(b) (4), (b) (6)	28 Oct 2020 17:55:23

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:15:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:15:45
Data point term sent to Coder	System	27 Oct 2020 18:49:38
User entered 'Pulmonary embolisms (right main pulmonary artery, lefts lower lobar branch)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms 15 OCT 2020. If not updating the start date, please clarify.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:54:29
	(b) (4), (b) (6)	10 Nov 2020 17:59:46
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms 15 OCT 2020. If not updating the start date, please clarify.' answered with 'updated for onset of symptoms' (Site from Safety).	Sharon Mathys (b) (4)	10 Nov 2020 13:00:45
User entered '15 Oct 2020' reason for change: Per Query Resolution	(b) (4)	09 Nov 2020 14:55:53
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms 15 OCT 2020. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:45:44
User entered '17 Oct 2020'	Sharon Mathys (b) (4)	27 Oct 2020 18:49:05
	(b) (4)	

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Yaman Ahmed (b) (4)	10 Nov 2020 18:24:47
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	10 Nov 2020 18:24:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	27 Oct 2020 18:49:05
	(b) (4)	

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 19:54:35
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 18:25:39
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Nov 2020 18:25:39
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'acute event, recovered; end date same as discharge' (Site from Safety).	Yaman Ahmed (b) (4)	10 Nov 2020 18:25:11
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Nov 2020 18:24:47
DataPoint Un-verified.	Yaman Ahmed (b) (4)	10 Nov 2020 18:24:47
User entered '19 Oct 2020' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	10 Nov 2020 18:24:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:45:11
User entered empty.	Sharon Mathys (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		27 Oct 2020 18:49:20
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	27 Oct 2020 18:49:05
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		27 Oct 2020 18:49:05
User entered '1'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '17 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '19 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Oct 2020 18:49:20
User entered empty.	Sharon Mathys (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '1'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 19:54:47
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'recovered from acute event' (Site from Safety).	Yaman Ahmed (b) (4)	10 Nov 2020 18:26:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	10 Nov 2020 18:25:39
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:46:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4)	27 Oct 2020 18:49:05

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Folder: Adverse Events

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Generated On: 26 Nov 2020 09:31:41

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Normocytic anemia is listed in discharge diagnosis. Does it meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:51:41
User closed query 'PV Query: Please kindly request further information whether hematological consult for possible hypercoagulative state was performed. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:51:36
Query 'PV Query: Normocytic anemia is listed in discharge diagnosis. Does it meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If not, please state so.' answered with 'Not serious at this time' (Site from Safety).	Sharon Mathys (b) (4)	10 Nov 2020 20:16:03
Query 'PV Query: Please kindly request further information whether hematological consult for possible hypercoagulative state was performed. If not, please state so.' answered with 'Hematologic consult took place 09 Nov 2020 and it was recommended he continue on the Eliquis and according to specialist will be investigated further ' (Site from Safety).	Sharon Mathys (b) (4)	10 Nov 2020 20:09:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'FROM DISCHARGE: 62 YO. PRESENTED?TO THE HOSPITAL FOR LEFT FLANK/UPPER ABDOMINAL?PAIN 10/17/2020. SYMPTOMS STARTED 2 DAYS PRIOR (10/15/2020). ?INITIALLY DESCRIBED AS AN ACHY LIKE SENSATION ON THE LEFT UPPER ABDOMINAL/FLANK REGION. ?THOUGHT IT WAS LIKELY MUSCULOSKELETAL. ?THE FOLLOWING DAY IS A LITTLE BIT WORSE TOOK CELEBREX. ?THAT EVENING THE PAIN GOT SEVERE WITH SOME DIFFICULTY WITH BREATHING. ?PAIN MEDICATION DID NOT ALLEVIATE THE SYMPTOM. ?HE THOUGHT HE WAS HAVING A KIDNEY STONE GIVEN HIS HISTORY OF NEPHROLITHIASIS. ?HE STATES WHEN EMS ARRIVED AND HE WAS GIVEN FENTANYL THAT HELPS ALLEVIATE HIS SYMPTOMS. ?HE DENIES ANY LONG TRAVELS PRIOR TO HIS SYMPTOMS STARTING. ?DENIES FAMILY HISTORY OF BLOOD CLOTS. ?DENIES RECENT SURGERY, IMMOBILITY. ?VITALS ON ARRIVAL WITH TACHYCARDIA.??LABORATORY STUDIES WITH SLIGHT BNP ELEVATION, SLIGHT LEUKOCYTOSIS, SLIGHT NORMOCYTIC ANEMIA. ?CT IMAGING WITH RESULTS BELOW REVEALING PE AND OPACITIES CONCERNING FOR POSSIBLE INFARCTION OR ATELECTASIS. ?PATIENT WAS STARTED ON HEPARIN, AVELOX ORDERED, COVID-19 SWAB DONE, AND HE WAS ADMITTED FOR FURTHER MANAGEMENT. HEMODYNAMICALLY STABLE. BP NORMAL RANGE. NOT REQUIRING OXYGEN PRESENTLY.?NO RIGHT HEART?STRAIN NOTED ON IMAGING. TROP <18, BNP 58??.?STARTED ON?ENOXAPARIN.??2D ECHO?SHOWED NORMAL EF WITHOUT RV STRAIN. ?PULMONARY WAS CONSULTED. BILATERAL VENOUS DOPPLER?WERE NEGATIVE FOR ANY ACUTE DVT.??IT IS NOT	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 19:01:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
CLEAR WHY THIS PATIENT HAD LARGE PULMONARY EMBOLISM?HOWEVER HE DID HAVE SEDENTARY LIFESTYLE OVER THE LAST 6 MONTHS. ?HE IS UP-TO-DATE ON HIS CANCER SCREENING. ?HE HAS NO RESPIRATORY ILLNESS TO SUGGEST COVID-19. ?HIS COVID-19 WAS NEGATIVE?AND HIS ANTIBODIES WERE NEGATIVE AS WELL. ?HE WAS SWITCHED TO ELIQUIS. ?ADVISED TO FOLLOW-UP WITH HEMATOLOGY FOR HYPERCOAGULABLE WORKUP. DISCHARGED 10/19/2020. Hematologic consult was completed on 09 Nov 2020. Recommended that he continue with Eliquis. CURRENTLY ON ELIQUIS 5 MG TWICE A DAY (per EPIC started on 04 Nov 2020)' reason for change: New Information DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 18:27:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'FROM DISCHARGE: 62 YO. PRESENTED?TO THE HOSPITAL FOR LEFT FLANK/UPPER ABDOMINAL?PAIN 10/17/2020. SYMPTOMS STARTED 2 DAYS PRIOR (10/15/2020). ?INITIALLY DESCRIBED AS AN ACHY LIKE SENSATION ON THE LEFT UPPER ABDOMINAL/FLANK REGION. ?THOUGHT IT WAS LIKELY MUSCULOSKELETAL. ?THE FOLLOWING DAY IS A LITTLE BIT WORSE TOOK CELEBREX. ?THAT EVENING THE PAIN GOT SEVERE WITH SOME DIFFICULTY WITH BREATHING. ?PAIN MEDICATION DID NOT ALLEVIATE THE SYMPTOM. ?HE THOUGHT HE WAS HAVING A KIDNEY STONE GIVEN HIS HISTORY OF NEPHROLITHIASIS. ?HE STATES WHEN EMS ARRIVED AND HE WAS GIVEN FENTANYL THAT HELPS ALLEVIATE HIS SYMPTOMS. ?HE DENIES ANY LONG TRAVELS PRIOR TO HIS SYMPTOMS STARTING. ?DENIES FAMILY HISTORY OF BLOOD CLOTS. ?DENIES RECENT SURGERY, IMMOBILITY. ?VITALS ON ARRIVAL WITH TACHYCARDIA.??LABORATORY STUDIES WITH SLIGHT BNP ELEVATION, SLIGHT LEUKOCYTOSIS, SLIGHT NORMOCYTIC ANEMIA. ?CT IMAGING WITH RESULTS BELOW REVEALING PE AND OPACITIES CONCERNING FOR POSSIBLE INFARCTION OR ATELECTASIS. ?PATIENT WAS STARTED ON HEPARIN, AVELOX ORDERED, COVID-19 SWAB DONE, AND HE WAS ADMITTED FOR FURTHER MANAGEMENT. HEMODYNAMICALLY STABLE. BP NORMAL RANGE. NOT REQUIRING OXYGEN PRESENTLY.?NO RIGHT HEART?STRAIN NOTED ON IMAGING. TROP <18, BNP 58??.?STARTED ON?ENOXAPARIN.??2D ECHO?SHOWED NORMAL EF WITHOUT RV STRAIN. ?PULMONARY WAS CONSULTED. BILATERAL VENOUS DOPPLER?WERE NEGATIVE FOR ANY ACUTE DVT.??IT IS NOT	Yaman Ahmed (b) (4) (b) (4)	10 Nov 2020 18:27:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
CLEAR WHY THIS PATIENT HAD LARGE PULMONARY EMBOLISM?HOWEVER HE DID HAVE SEDENTARY LIFESTYLE OVER THE LAST 6 MONTHS. ?HE IS UP-TO-DATE ON HIS CANCER SCREENING. ?HE HAS NO RESPIRATORY ILLNESS TO SUGGEST COVID-19. ?HIS COVID-19 WAS NEGATIVE?AND HIS ANTIBODIES WERE NEGATIVE AS WELL. ?HE WAS SWITCHED TO ELIQUIS. ?ADVISED TO FOLLOW-UP WITH HEMATOLOGY FOR HYPERCOAGULABLE WORKUP. DISCHARGED 10/19/2020. Currently on Eliquis 5 mg twice a day' reason for change: New Information DataPoint Verified.		
	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User opened query 'PV Query: Normocytic anemia is listed in discharge diagnosis. Does it meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:51:26
User opened query 'PV Query: Please kindly request further information whether hematological consult for possible hypercoagulative state was performed. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:51:12
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Oct 2020 19:18:13
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	27 Oct 2020 19:18:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User entered 'from discharge; 62 yo. presented?to the hospital for left flank/upper abdominal?pain 10/17/2020. ?Symptoms started 2 days prior (10/15/2020). ?Initially described as an achy like sensation on the left upper abdominal/flank region. ?Thought it was likely musculoskeletal. ?The following day is a little bit worse took Celebrex. That evening the pain got severe with some difficulty with breathing. ?Pain medication did not alleviate the symptom. ?He thought he was having a kidney stone given his history of nephrolithiasis. ?He states when EMS arrived and he was given fentanyl that helps alleviate his symptoms. ?He denies any long travels prior to his symptoms starting. ?Denies family history of blood clots. ?Denies recent surgery, immobility. ?Vitals on arrival with tachycardia.??Laboratory studies with slight BNP elevation, slight leukocytosis, slight normocytic anemia. ?CT imaging with results below revealing PE and opacities concerning for possible infarction or atelectasis. ?Patient was started on heparin, Avelox ordered, COVID-19 swab done, and he was admitted for further management. Hemodynamically stable. BP normal range. Not requiring oxygen presently.?No right heart?strain noted on imaging. Trop <18, bnp 58??.?started on?enoxaparin.??2D echo?showed normal EF without RV strain. ?Pulmonary was consulted. bilateral venous Doppler?were negative for any acute DVT.??It is not clear why this patient had large pulmonary embolism?however he did have sedentary lifestyle over the last 6 months. ?He is up-to-date on his cancer screening. ?He has no respiratory illness to suggest COVID-19. ?His COVID-19 was negative?and his antibodies were negative as well. He was switched to Eliquis. ?Advised to follow-up with hematology for hypercoagulable workup. discharged 10/19/2020. Has not followed up with staff on resolution.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:18:13
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Oct 2020 18:49:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:49:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 18:49:05

US3522077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:31:41

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 18:49:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:31:41

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:07:46
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:41:56

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:44:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:44:08
Data point term sent to Coder	System	11 Aug 2020 13:43:04
User entered 'gabapentin'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered 'migraines'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered '200'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered 'once daily (QD)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered '1'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Oct 2020 19:05:50
User entered 'Yes (Y)'	Alandra White (b) (4)	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered '17 Oct 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Oct 2020 19:05:50
User entered empty.	(b) (4)	
	Alandra White (b) (4)	11 Aug 2020 13:42:57
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:00:31
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:42:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:42:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:42:57

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 13:42:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: VERAPAMIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:56:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:56:16
Data point term sent to Coder	System	11 Aug 2020 13:44:06
User entered 'verapamil'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered 'migraines'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered '40'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered 'three times daily (TID)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered '1'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:53
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 13:43:46

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EVOLOCUMAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:18:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:18:13
Data point term sent to Coder	System	11 Aug 2020 13:46:11
User entered 'evolocumab'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered 'hyperlipidemia'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered '140'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered 'other (OTHER)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered 'once every 14 days'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered '1'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered empty.	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:04:58
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:45:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE RHA 3V (BACULOVIRUS), PRODUCTSYNONYM: FLUBLOK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:18:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:18:39
Data point term sent to Coder	System	27 Oct 2020 18:01:14
User entered 'Flublok RIV 4'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered 'Prevention of Influenza'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered '0.5'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered 'mL (mL)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered 'once (ONCE)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered 'Intramuscular (INTRAMUSCULAR)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered '18 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered '18 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:50
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:00:27

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:14:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:14:36
Data point term sent to Coder	System	27 Oct 2020 18:53:47
User entered 'enoxaparin'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered 'Pulmonary Embolisms'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered '90' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Oct 2020 18:56:19
User entered '1'	(b) (4)	
	Sharon Mathys (b) (4)	27 Oct 2020 18:53:15
	(b) (4)	

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered 'mg (mg)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Oct 2020 18:56:19
User entered 'Other (OTHER)'	Sharon Mathys (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	27 Oct 2020 18:56:19
User entered 'mg/kg'	Sharon Mathys (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered 'every 12 hours'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered 'Subcutaneous (SUBCUTANEOUS)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered '17 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered '19 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:05:54
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:53:15

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:07:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:07:46
Data point term sent to Coder	System	27 Oct 2020 18:55:51
User entered 'Heparin'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'Pulmonary Embolism'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered '25000'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'units in dextrose'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'continuous'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered '17 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered '17 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:55:39

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: MOXIFLOXACIN HYDROCHLORIDE, PRODUCTSYNONYM: AVELOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:25:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:25:35
Data point term sent to Coder	System	27 Oct 2020 18:57:58
User entered 'avelox'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered 'Pulmonary Embolism'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered '400'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered 'once (ONCE)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered 'Intravenous (INTRAVENOUS)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered '17 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered '17 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:28
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 18:57:50

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:02:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:02:25
Data point term sent to Coder	System	27 Oct 2020 19:01:02
User entered 'Tylenol'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'pulmonary embolisms' reason for change: Data Entry Error	Sharon Mathys (b) (4)	27 Oct 2020 19:00:21
User entered 'Pain'	(b) (4)	
	Sharon Mathys (b) (4)	27 Oct 2020 19:00:10
	(b) (4)	

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'variable'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'dose varied between 975 mg and 650 mg'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'every 8 hours'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered '18 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered '19 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:32
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:00:10

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:14:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:14:58
Data point term sent to Coder	System	27 Oct 2020 19:03:06
User entered 'morphine'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered 'Pulmonary Embolism'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered '4'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered 'twice daily (BID)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered 'Intravenous (INTRAVENOUS)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered '17 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered '18 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 19:02:54

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:18:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:18:28
Data point term sent to Coder	System	27 Oct 2020 19:06:11
User entered 'gabapentin'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered 'pulmonary embolism'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered '200'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered '17 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered '18 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:38
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 19:05:30

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:12:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:12:32
Data point term sent to Coder	System	27 Oct 2020 19:11:17
User entered 'eliquis'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered 'Pulmonary Embolisms'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered '5'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered 'two tablets twice daily for 7 days, one tablet twice daily ongoing'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered '19 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:42
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:10:25

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:09:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 19:09:35
Data point term sent to Coder	System	27 Oct 2020 19:08:15
User entered 'gabapentin'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered 'Migraine'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered '100'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered 'other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered 'once in morning, twice at night'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered '19 Oct 2020'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered '0'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered empty.	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:08:58
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:07:51

US3522077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:31:41

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 19:07:51

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'USA-US131-2020-MRNA-1273-P301000009'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Yes (Y)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Yes (Y)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Paul'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Kilgore'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'MI'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:55:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
User entered 'US'	System	28 Oct 2020 17:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 19:55:46
User entered '1'	System	28 Oct 2020 17:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'USA-US131-2020-MRNA-1273-P301000009'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Yes (Y)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Yes (Y)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Paul'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Kilgore'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'MI'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:55:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
User entered 'US'	System	28 Oct 2020 17:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 19:55:46
User entered '1'	System	28 Oct 2020 17:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
User entered '28/Oct/2020 17:55'	System	28 Oct 2020 17:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:31:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:55:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 17:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'USA-US131-2020-MRNA-1273-P301000009'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Yes (Y)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Yes (Y)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'No (N)'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Paul'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'Kilgore'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered 'MI'	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:55:41
User entered (b) (6)	System	28 Oct 2020 17:55:23

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 19:55:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:17
User entered 'US'	System	28 Oct 2020 17:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 26 Nov 2020 09:31:41

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 19:55:46
User entered '1'	System	28 Oct 2020 17:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:41

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '10/Nov/2020 19:55'	System	10 Nov 2020 19:55:46

US3522077

Folder: SAE USA-US131-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:31:41

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 19:55:46