

US3222077 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:06:55

All time stamps listed in this document are displayed in GMT

US3222077

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 15:36:28

Generated On: 09 Jun 2021 16:06:55

[Participant ID](#)

US3222077

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

US3222077

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 15:36:52

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Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 15:36:52

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 15:36:53

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 15:36:52

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Condition	APPENDECTOMY
Start date (dd MMM yyyy)	01 JAN 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JAN 1966
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	01 JAN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Condition	COPD-CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	01 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Condition	DIABETES MELLITUS TYPE II
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	01 JAN 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Condition	LUNG NODULE BENIGN
Start date (dd MMM yyyy)	01 JAN 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3222077

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Condition	NEPHROLITHIASIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3222077

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:05 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:05
Height (<i>xxx.x</i>)	168.3 cm
Weight (<i>xxx.x</i>)	96.8 kg
BMI (<i>xxx.x</i>)	34.17489 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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

Data signed: (b) (4) 19 Feb 2021 15:36:53

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:36:53

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185546

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

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	17:05 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:05
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 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: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	19:09 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 19:09
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 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: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 AUG 2020

What was the treatment time? (00:00-23:59) 18:39 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 18:39

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

18:15 (24 HR)

Collection date and time (derived)

10 AUG 2020 18:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:19	10 AUG 2020 18:19
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

10 AUG 2020 19:02

PC Open Date & Time

10 AUG 2020 18:59

PC Close Date & Time

10 AUG 2020 21:29

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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 10 AUG 2020 22:24

PC Close Date & Time 11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 20:23

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

12 AUG 2020 20:02

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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 20:19

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 20:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 18:34

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

16 AUG 2020 19:22

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 19:03

PC Open Date & Time

10 AUG 2020 18:59

PC Close Date & Time

10 AUG 2020 21:29

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

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

PC Open Date & Time

10 AUG 2020 22:24

PC Close Date & Time

11 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

11 AUG 2020 20:28

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 20:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 20:20

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 20:24

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 18:34

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 19:23

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 19:03
PC Open Date & Time	10 AUG 2020 18:59
PC Close Date & Time	10 AUG 2020 21:29

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 22:24

PC Close Date & Time

11 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:04
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 20:20
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2889

EAB) (1725)

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:25
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 2889

EAB) (1725)

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 18:35
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2889

EAB) (1725)

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:24
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3222077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	16:16 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 16:16
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	17:48 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 17:48
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3222077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 9 SEP 2020

What was the treatment time? (00:00-23:59) 17:18 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 17:18

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

US3222077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 SEP 2020

Collection time (00:00-23:59)

16:40 (24 HR)

Collection date and time (derived)

9 SEP 2020 16:40

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:41	9 SEP 2020 16:41
Nasopharyngeal Swab 2	No		

US3222077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

09 SEP 2020 19:03

PC Open Date & Time

09 SEP 2020 17:38

PC Close Date & Time

09 SEP 2020 20:08

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

09 SEP 2020 21:03

PC Close Date & Time

10 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 18:51

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 19:39

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 18:55

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:20

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 19:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 20:30

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:04

PC Open Date & Time

09 SEP 2020 17:38

PC Close Date & Time

09 SEP 2020 20:08

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

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

PC Open Date & Time

09 SEP 2020 21:03

PC Close Date & Time

10 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

8

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

10 SEP 2020 18:55

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

11 SEP 2020 19:40

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

6

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

12 SEP 2020 18:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

6

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

13 SEP 2020 19:21

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

4

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

14 SEP 2020 19:35

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

15 SEP 2020 20:27

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 19:06
PC Open Date & Time	09 SEP 2020 17:38
PC Close Date & Time	09 SEP 2020 20:08

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☐
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☐
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 21:03

PC Close Date & Time

10 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:56
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 19:41
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:53
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:22
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:36
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☒

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

		Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 20:30	
PC Open Date & Time	15 SEP 2020 12:00	
PC Close Date & Time	16 SEP 2020 11:59	

US3222077

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 8
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time stamp	16 SEP 2020 18:52
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 16 SEP 2020 18:49

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

16 SEP 2020 18:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 19:30

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 SEP 2020 20:20

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

20 SEP 2020 06:28

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

20 SEP 2020 12:07

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:39

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:11

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

23 SEP 2020 12:01

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

24 SEP 2020 18:53

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

26 SEP 2020 09:35

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

26 SEP 2020 12:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

28 SEP 2020 12:00

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

29 SEP 2020 12:21

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

30 SEP 2020 22:42

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

01 OCT 2020 12:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

02 OCT 2020 12:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

03 OCT 2020 12:00

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

04 OCT 2020 12:00

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

05 OCT 2020 22:38

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

06 OCT 2020 12:05

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 OCT 2020 17:21

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

08 OCT 2020 12:00

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

09 OCT 2020 14:25

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

11 OCT 2020 10:25

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(33)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 33

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(34)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 34

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 16 SEP 2020 18:50

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 17 SEP 2020 19:30

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 SEP 2020 20:20

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☒

PC Time stamp

16 SEP 2020 18:50

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp

17 SEP 2020 19:31

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 10

Select one response below to indicate the level of your

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 ☐

PC Time stamp

18 SEP 2020 20:20

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 11

Select one response below to indicate the level of your

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 ☐

PC Time stamp

20 SEP 2020 06:28

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 12

Select one response below to indicate the level of your

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 ☐

PC Time stamp

20 SEP 2020 12:07

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 13

Select one response below to indicate the level of your

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 ☐

PC Time stamp

21 SEP 2020 21:39

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 14

Select one response below to indicate the level of your

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 ☐

PC Time stamp

22 SEP 2020 12:11

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 15

Select one response below to indicate the level of your

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 ☐

PC Time stamp 23 SEP 2020 12:01

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 16

Select one response below to indicate the level of your

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 ☐

PC Time stamp

24 SEP 2020 18:53

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 17

Select one response below to indicate the level of your

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 ☐

PC Time stamp

26 SEP 2020 09:35

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 18

Select one response below to indicate the level of your

None ☒

NAUSEA/VOMITING

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 ☐

PC Time stamp

26 SEP 2020 12:00

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you
are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time	16 SEP 2020 12:00
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PC Close Date & Time	17 SEP 2020 11:59
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PC Time stamp	16 SEP 2020 18:51
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US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	16 SEP 2020 18:51
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	17 SEP 2020 19:31
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 20:21
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 06:28
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 SEP 2020 12:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 SEP 2020 21:40
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	22 SEP 2020 12:11
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	23 SEP 2020 12:01
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	24 SEP 2020 18:54
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	26 SEP 2020 09:36
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 SEP 2020 12:00
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	28 SEP 2020 12:00
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	29 SEP 2020 12:21
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	30 SEP 2020 22:42
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 23

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

No ☐

Yes ☒

PC Time stamp

01 OCT 2020 12:02

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 12:01
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 OCT 2020 12:00
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 OCT 2020 12:00
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 OCT 2020 22:38
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 12:05
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	07 OCT 2020 17:21
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	08 OCT 2020 12:00
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 14:25
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 OCT 2020 10:25
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 33
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 34
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3222077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3222077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	07:48 (24 HR)
Collection date and time (derived)	7 OCT 2020 07:48

US3222077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:53

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 OCT 2020 10:25:20
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 OCT 2020 12:35:42
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 01:43:50

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 07:00:25
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 19:21:10
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 21:53:38

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 09:28:57

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 17:59:31
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 00:05:39
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 12:58:56

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 13:35:29

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 12:33:58

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 11:20:35
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 18:25:49
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 19:44:24
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 173

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 187

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 236

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Patient Cloud Open Date & Time	24 NOV 2021 00:01
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Patient Cloud Close Date & Time	28 NOV 2021 23:59
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US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Patient Cloud Open Date & Time	08 DEC 2021 00:01
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Patient Cloud Close Date & Time	12 DEC 2021 23:59
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US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Patient Cloud Open Date & Time	15 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Patient Cloud Open Date & Time	22 DEC 2021 00:01
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Patient Cloud Close Date & Time	26 DEC 2021 23:59
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US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 537

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

Patient Cloud Open Date & Time	03 AUG 2022 00:01
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Patient Cloud Close Date & Time	07 AUG 2022 23:59
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US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3222077

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:06:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3222077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:36:52

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3222077

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3222077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

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

Collection date (dd MMM yyyy)	24 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	7:30 (24 HR)
-------------------------------	--------------

Collection date and time (derived)	24 FEB 2021 7:30
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US3222077

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222077

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222077

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222077

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:06:55

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3222077

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:06:55

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222077

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

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

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3222077

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Date of updated informed consent (dd MMM yyyy) 15 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 15 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3222077

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

15 JAN 2021 14:00

US3222077

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

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

Collection date (dd MMM yyyy)	15 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	14:05
---------------------------------	-------

Collection Date and Time (derived)	15 JAN 2021 14:05
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US3222077

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 15:36:31

Generated On: 09 Jun 2021 16:06:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

AEID	USA-US104-2020-MRNA-1273-P30 1000004
Adverse event	KIDNEY STONES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	2 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	22 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

SUBJECT WENT TO THE ER FOR
KIDNEY STONES HE SAID IT
WAS COMING ON "COULD FEEL
IT AND I WANTED TO SEEK
TREATMENT BEFORE IT GOT
BAD. HE RATED IT A
MODERATE GRADE 2. HE WAS
GIVEN MORPHINE, AND FLUIDS
AND OXYCOTIN AT
DISCHARGE SAME DAY. NOT
AN SAE,
I FIRST FOUND OUT TODAY
27/SEP/2020 @ 12:05 PM WHILE
CALLING PATIENT ABOUT A
SOLICITED EVENT.
SUBJECT WENT TO THE ER FOR
KIDNEY STONES ON
18/SEP/2020. HE SAID IT WAS
COMING ON "COULD FEEL IT
AND I WANTED TO SEEK
TREATMENT BEFORE IT GOT
BAD. HE RATED IT A
MODERATE GRADE 2. HE WAS
GIVEN MORPHINE, AND FLUIDS
AND OXYCOTIN AT
DISCHARGE SAME DAY. I
RECORDED THIS EVENT AS AN
ADVERSE EVENT.
CORRECTED DISCHARGE DATE
WITH MEDICAL RECORDS
RECEIVED. THEN HE WENT
BACK TO THE ER ON
22/SEP/2020 FOR KIDNEY
STONES AND WAS ADMITTED
AND DISCHARGED ON
23/SEP/2020. HE WAS
DISCHARGED WITHOUT
PASSING THE STONE AND IS
SCHEDULED FOR LITHOTRIPSY
ON 02/OCT/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

PRODUCTION RELEASE (v12.003

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US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

AEID

Adverse event

URINARY TRACT INFECTION

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)

22 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 SEP 2020
Start time (00:00-23:59)	12:00 (24 HR)
AE start date and time (derived)	10 SEP 2020 12:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 OCT 2020
End time (00:00-23:59)	12:00 (24 HR)
AE End Date and Time (derived)	11 OCT 2020 12:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

AEID

Adverse event

MUSCLE ACHES (MYALGIA
WHOLE BODY)

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)

11 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

AEID

Adverse event

NAUSEA/ VOMITING

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 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

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

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 25 Mar 2021 17:13:28

Generated On: 09 Jun 2021 16:06:55

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

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 Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication AFLUZOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATE
HYPERPLASIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CONGESTIVE HEART FAILURE

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2000
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication BREO ELLIPTA

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2014
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication CETIRIZINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATE
HYPERPLASIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication LOVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2010
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2013
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 13:39:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2002	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication POTASSIUM

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 99

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication VITAMIN B COMPLEX

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2002	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication OXYCONTIN

Prophylaxis Yes ☒
No ☐

Indication KIDNEY STONES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication MORPHINE DRIP

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication EMPIRIC ANTIBIOTIC
THERAPY(UNKNOWN)

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration UNK

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

If dose unit is Other, specify DOSE NOT PROVIDED

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 ☐

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication IV FLUIDS

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONES

Dose per administration UNK

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

If dose unit is Other, specify DOSE IS UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication RENAL PAIN SECONDARY TO
KIDNEY STONE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication INFLUENZA

Prophylaxis Yes ☒
No ☐

Indication VACCINE

Dose per administration .05

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 13:39:07

Generated On: 09 Jun 2021 16:06:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 OCT 2020	LITHOTRIPSY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:06:55

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:06:55

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	28/SEP/2020 10:12
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	30/SEP/2020 12:36
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	12/OCT/2020 13:26
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	12/OCT/2020 13:30
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	13/OCT/2020 15:53
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	20/OCT/2020 14:05
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	20/OCT/2020 13:48
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.	False

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	21/OCT/2020 14:00
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	21/OCT/2020 17:33
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/NOV/2020 14:56
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	02/DEC/2020 12:14
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

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (13)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	
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.	False

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Data signed: (b) (4) 19 Feb 2021 15:36:32

Generated On: 09 Jun 2021 16:06:55

SAEID	USA-US104-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	21/DEC/2020 10:17
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

US3222077 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222077

Form: Participant Creation

Generated On: 09 Jun 2021 16:06:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'US3222077'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 21:39:24

US3222077

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:26:16

US3222077

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 21:39:25

US3222077

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:26:16

US3222077

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'SCRN'	System	10 Aug 2020 22:26:16

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 21:39:25

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '73'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'YEARS'	System	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '73'	System	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Male (M)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'I'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:06:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:08

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Aug 2020'	System	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '2020'	System	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Amendment 1 (1)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 21:39:25

US3222077

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:06:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'I'	System	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:06:55

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:26:21

US3222077

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:06:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:20

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:30:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:30:21
Data point term sent to Coder	System	10 Aug 2020 23:13:21
User entered 'Appendectomy'	Crystal Paccione (b) (4)	10 Aug 2020 23:12:50

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '01 Jan 1966'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:12:50

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:50

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 16:59:58
User entered 'Yes (Y)'	Albert Garcia (b) (4)	10 Aug 2020 23:12:50
	(b) (4)	

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '01 Jan 1966' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 16:59:58
User entered empty.	Albert Garcia (b) (4)	10 Aug 2020 23:12:50
	(b) (4)	

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:12:50

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 1966'	System	10 Aug 2020 23:12:50

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '1966'	System	10 Aug 2020 23:12:50

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 1966'	System	12 Oct 2020 16:59:58
User entered empty.	System	10 Aug 2020 23:12:50

US3222077

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '1966'	System	12 Oct 2020 16:59:58
User entered empty.	System	10 Aug 2020 23:12:50

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:31:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:31:01
Data point term sent to Coder	System	10 Aug 2020 23:14:23
User entered 'Benign Prostatic Hyperplasia'	Crystal Paccione (b) (4)	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '01 Jan 2018'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 2018'	System	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '2018'	System	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:13:37

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:54:38
Query 'Per DM CLR: Please note that there is no Con Crystal Paccione Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'DATA ADDED' (Site from DM).	(b) (4) (b) (4)	18 Sep 2020 16:52:56
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:21:57
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:31:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:31:01
Data point term sent to Coder	System	10 Aug 2020 23:14:23
User entered 'Congestive heart failure'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'un UNK 2018' reason for change:	(b) (4)	
Data Entry Error	gail lavine (b) (4)	01 Dec 2020 14:34:25
User entered '01 Jan 2018'	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 23:14:07
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 2018'	System	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '2018'	System	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:14:07

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:56:20
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'DATA ADDED' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:53:09
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:22:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:28:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:28:16
Data point term sent to Coder	System	10 Aug 2020 23:15:26
User entered 'COPD-Chronic Obstructive Pulmonary Disease'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '01 Jan 2014'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 2014'	System	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '2014'	System	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:15:02

US3222077

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:59:33
User closed query 'Per DM CLR: Please specify appropriately the type of Diabetes Mellitus (e.g. Type I or Type II). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 19:59:31
Query 'Per DM CLR: Please note that there is no Con Crystal Paccione Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'DATA ADDED' (Site from DM).	(b) (4)	18 Sep 2020 16:53:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:21:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 21:21:49
Data point term sent to Coder	System	15 Sep 2020 21:20:51
Query 'Per DM CLR: Please specify appropriately the type of Diabetes Mellitus (e.g. Type I or Type II). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:18
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:14
User entered 'DIABETES MELLITUS TYPE II' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:14

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:22:39
User opened query 'Per DM CLR: Please specify appropriately the type of Diabetes Mellitus (e.g. Type I or Type II). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:22:30
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:31:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:31:30
Data point term sent to Coder	System	10 Aug 2020 23:16:31
User entered 'Diabetes Mellitus type II'	Crystal Paccione (b) (4)	10 Aug 2020 23:15:55

US3222077

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'UN UNK 2002' reason for change:	(b) (4)	
Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:47:00
User entered empty.	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 23:15:55
	(b) (4)	

US3222077

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 16:47:27
User entered '0' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:47:27
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 16:47:00
User entered '1'	Crystal Paccione (b) (4)	10 Aug 2020 23:15:55
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:15:55

US3222077

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:15:55

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:15:55

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 2002'	System	19 Oct 2020 16:47:00
User entered empty.	System	10 Aug 2020 23:15:55

US3222077

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '2002'	System	19 Oct 2020 16:47:00
User entered empty.	System	10 Aug 2020 23:15:55

US3222077

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:15:55

US3222077

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:15:55

US3222077

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:32:12
Data point term sent to Coder	System	10 Aug 2020 23:17:32
User entered 'Hypercholesterolemia'	Crystal Paccione (b) (4)	10 Aug 2020 23:16:34

US3222077

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '01 Jan 2010'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:16:34

US3222077

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:16:34

US3222077

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:16:34

US3222077

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:16:34

US3222077

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:16:34

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 2010'	System	10 Aug 2020 23:16:34

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '2010'	System	10 Aug 2020 23:16:34

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:16:34

US3222077

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:16:34

US3222077

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per DM CLR: Please update the condition to confirm if the Nodule was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 20:08:23
User closed query 'Per DM CLR: Please specify laterality of affected lung (i.e. Left, Right or Bilateral) and include in MH term as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 20:08:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms benign (excl mesotheliomas), HLT: Respiratory tract and pleural neoplasms benign NEC, PT: Benign lung neoplasm, LLT: Benign lung neoplasm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:50:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:50:48
Query 'Per DM CLR: Please specify laterality of affected lung (i.e. Left, Right or Bilateral) and include in MH term as appropriate. Otherwise, provide comment.' answered with 'UNKNOWN' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:54:14
Data point term sent to Coder	System	18 Sep 2020 16:54:12
Query 'Per DM CLR: Please update the condition to confirm if the Nodule was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'DATA ADDED' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:54:03
Coding entries removed.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:53:54
User entered 'LUNG NODULE BENIGN' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:53:54

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify laterality of affected lung (i.e. Left, Right or Bilateral) and include in MH term as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:23:05
User opened query 'Per DM CLR: Please update the condition to confirm if the Nodule was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 05:22:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Pulmonary mass, LLT: Lung nodule - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:13
Data point term sent to Coder	System	10 Aug 2020 23:17:34
User entered 'Lung Nodule'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:17:05

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '01 Jan 2014'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:17:05

US3222077

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:17:05

US3222077

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:17:05

US3222077

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:17:05

US3222077

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:17:05

US3222077

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 2014'	System	10 Aug 2020 23:17:05

US3222077

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '2014'	System	10 Aug 2020 23:17:05

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:17:05

US3222077

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	10 Aug 2020 23:17:05

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 16:53:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 16:53:53
Data point term sent to Coder	System	18 Sep 2020 16:53:06
User entered 'SEASONAL ALLERGIES'	Crystal Paccione (b) (4)	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'UN UNK 1995'	(b) (4) Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4)	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 1995'	System	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '1995'	System	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	18 Sep 2020 16:52:38

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
Query 'Per DM CLR: Please specify the laterality of NEPHROLITHIASIS (right, left or bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:20:31
User opened query 'Per DM CLR: Please specify the laterality of NEPHROLITHIASIS (right, left or bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:49:49
User coded data point as SOC: Renal and urinary disorders, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:18:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:18:33
Data point term sent to Coder	System	19 Oct 2020 19:17:11
User entered 'NEPHROLITHIASIS'	douglas winter (b) (4) (b) (4)	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'UN UNK 2010'	(b) (4) douglas winter (b) (4) (b) (4)	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'Jan 2010'	System	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '2010'	System	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:06:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	19 Oct 2020 19:17:09

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:10

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:10

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '17:05'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:10

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '10 Aug 2020 17:05'	System	10 Aug 2020 23:19:10

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '168.3' cm	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:19:10
DataPoint set to visible.	(b) (4) System	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '96.8' kg	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:19:10
DataPoint set to visible.	(b) (4) System	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
Amendment Manager: User entered '34.17489'	System	16 Sep 2020 23:50:54
User entered '34.2'	System	10 Aug 2020 23:19:10
DataPoint set to visible.	System	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'kg/m2'	System	10 Aug 2020 23:19:10
DataPoint set to visible.	System	10 Aug 2020 22:31:06

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:47:33
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:19:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:19:51
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:12:23
User entered '37.2' C	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:10

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	15 Sep 2020 21:19:51
User entered 'Oral (Oral)'	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 23:19:10
	(b) (4)	

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:10

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:19:51
User entered '71'	Albert Garcia (b) (4)	15 Sep 2020 21:19:51
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 23:19:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'bpm'	System	10 Aug 2020 23:19:10

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:19:51
User entered '18'	Albert Garcia (b) (4)	15 Sep 2020 21:19:51
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 23:19:10
	(b) (4)	

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'breaths/min'	System	10 Aug 2020 23:19:10

US3222077

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:19:51
User entered '158'	Albert Garcia (b) (4)	15 Sep 2020 21:19:51
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 23:19:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'mmHg'	System	10 Aug 2020 23:19:10

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 21:19:51
User entered '78'	Albert Garcia (b) (4)	15 Sep 2020 21:19:51
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 23:19:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'mmHg'	System	10 Aug 2020 23:19:10

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42

US3222077

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:19:22

US3222077

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:19:47
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 21:49:01
User entered '10 Aug 2020'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:22

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	(b) (4) Jennifer Dittman (b) (4) (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Retired'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'I'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:06:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 22:31:54

US3222077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:26:35

US3222077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	Jennifer Dittman (b) (4)	10 Aug 2020 22:26:35

US3222077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:26:35

US3222077

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'VISIT1'	System	10 Aug 2020 22:26:35

US3222077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:55

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:29:11

US3222077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:55

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:26:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:26:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 22:29:11
User entered '185546' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:29:11

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 22:29:11

US3222077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:55

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:19:44

US3222077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:55

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:19:44

US3222077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:55

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:44

US3222077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:44

US3222077

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:06:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:19:44

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:45
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:53
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:25
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:25
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:52
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:16:52
User entered '168.3' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:47
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:53
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:37
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:37
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:51:02
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:44
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:17:00
User entered '96.8' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:45
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:53
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:25
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:25
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:52
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:16:52
User entered '168.3' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:47
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:53
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:37
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:37
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:51:02
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:44
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:17:00
User entered '96.8' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User accepted default value 'Pre-Dose (PREDOSE)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '17:05'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '10 Aug 2020 17:05'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '37.2' C	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '71'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'bpm'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '18'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'breaths/min'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Aug 2020 09:21:31
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Amber Vasquez (b) (4) (b) (4)	21 Aug 2020 14:07:40
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Aug 2020 23:21:37
User entered '158'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'mmHg'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '78'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'mmHg'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:45
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:53
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:25
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:25
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:52
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:44
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:16:52
User entered '168.3' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:06:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:26:47
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 21:20:53
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:37
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:12:37
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:51:02
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 22:50:44
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:17:00
User entered '96.8' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User accepted default value 'Post-Dose (POSTDOSE)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed 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).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 08:29:37
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol correct' (Site from System).	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:22:09
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 23:21:37
User entered '19:09'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '10 Aug 2020 19:09'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '36.9' C	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '70'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'bpm'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '18'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'breaths/min'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Per CDM: "Kindly clarify if CS or NCS" ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Aug 2020 09:21:48
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 09:21:35
Query 'Per CDM: "Kindly clarify if CS or NCS" ' answered with 'NCS' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	21 Aug 2020 14:07:58
User opened query 'Per CDM: "Kindly clarify if CS or NCS" ' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 16:59:53
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS/NCS' (Site from System).	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:23:09
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	10 Aug 2020 23:21:37
User entered '160'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'mmHg'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '80'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'mmHg'	System	10 Aug 2020 23:21:37

US3222077

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:23:29

US3222077

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:23:29

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	Jennifer Dittman (b) (4)	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '18:39'	Jennifer Dittman (b) (4)	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '10 Aug 2020 18:39'	System	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'ONCE'	System	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 22:42:55

US3222077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:23:53

US3222077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:23:53

US3222077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '18:15'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:23:53

US3222077

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '10 Aug 2020 18:15'	System	10 Aug 2020 23:23:53

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:06:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 23:24:53

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:24:53

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:24:53

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	27 Aug 2020 11:40:06
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	27 Aug 2020 11:40:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Aug 2020 11:40:06
User entered '18:19' reason for change: Data Entry Error	douglas winter (b) (4)	27 Aug 2020 11:40:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	10 Aug 2020 23:24:53
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	10 Aug 2020 23:24:53
User entered '18:' (non-conformant).	Crystal Paccione (b) (4)	10 Aug 2020 23:24:53
	(b) (4)	

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '10 Aug 2020 18:19'	System	27 Aug 2020 11:40:06
User entered '10 Aug 2020 18:' (non-conformant).	System	10 Aug 2020 23:24:53

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:24:53

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Aug 2020 23:24:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 23:24:59
User entered 'No (N)' reason for change: Data Entry Error	Crystal Paccione (b) (4)	10 Aug 2020 23:24:59
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 23:24:53
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 23:24:53

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:24:53

US3222077

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered empty.	System	10 Aug 2020 23:24:53

US3222077

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:25:09

US3222077

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	10 Aug 2020 23:25:09

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:01:44', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '0a62bf45-3f44-4c88-bdf3-756d583f5db0' User entered 'Yes (Y)'	System	10 Aug 2020 23:02:17
	System	10 Aug 2020 23:02:17

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:01:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '0a62bf45-3f44-4c88-bdf3-756d583f5db0' User entered '98.5'	System	10 Aug 2020 23:02:17
	System	10 Aug 2020 23:02:17

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:02:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '0a62bf45-3f44-4c88-bdf3-756d583f5db0'	System	10 Aug 2020 23:02:17
User entered 'No (N)'	System	10 Aug 2020 23:02:17

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:02:14', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '0a62bf45-3f44-4c88-bdf3-756d583f5db0' User entered '10 Aug 2020 19:02'	System	10 Aug 2020 23:02:17
	System	10 Aug 2020 23:02:17

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 18:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 21:29'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 22:24'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 2'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:22:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4304f121-7c3e-4e74-99ff-08f781c37cb8' User entered 'Yes (Y)'	System	12 Aug 2020 00:23:02
	System	12 Aug 2020 00:23:02

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:22:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4304f121-7c3e-4e74-99ff-08f781c37cb8' User entered '97.7'	System	12 Aug 2020 00:23:02
	System	12 Aug 2020 00:23:02

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:22:50', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4304f121-7c3e-4e74-99ff-08f781c37cb8'	System	12 Aug 2020 00:23:02
User entered 'No (N)'	System	12 Aug 2020 00:23:02

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:23:00', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4304f121-7c3e-4e74-99ff-08f781c37cb8' User entered '11 Aug 2020 20:23'	System	12 Aug 2020 00:23:02
	System	12 Aug 2020 00:23:02

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 3'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:01:41', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3a47e657-06df-41d2-a5c8-b9cec53ecfa1' User entered 'Yes (Y)'	System	13 Aug 2020 00:02:07
	System	13 Aug 2020 00:02:07

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:01:51', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3a47e657-06df-41d2-a5c8-b9cec53ecfa1' User entered '98.0'	System	13 Aug 2020 00:02:07
	System	13 Aug 2020 00:02:07

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:01:57', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3a47e657-06df-41d2-a5c8-b9cec53ecfa1'	System	13 Aug 2020 00:02:07
User entered 'No (N)'	System	13 Aug 2020 00:02:07

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:02:04', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3a47e657-06df-41d2-a5c8-b9cec53ecfa1' User entered '12 Aug 2020 20:02'	System	13 Aug 2020 00:02:07
	System	13 Aug 2020 00:02:07

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 4'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:19:02', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1a168839-908e-4b11-bdc1-446954e93cbf' User entered 'Yes (Y)'	System	14 Aug 2020 00:19:22
	System	14 Aug 2020 00:19:22

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:19:10', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1a168839-908e-4b11-bdc1-446954e93cbf' User entered '98.7'	System	14 Aug 2020 00:19:22
	System	14 Aug 2020 00:19:22

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:19:16', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1a168839-908e-4b11-bdc1-446954e93cbf'	System	14 Aug 2020 00:19:22
User entered 'No (N)'	System	14 Aug 2020 00:19:22

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:19:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1a168839-908e-4b11-bdc1-446954e93cbf' User entered '13 Aug 2020 20:19'	System	14 Aug 2020 00:19:22
	System	14 Aug 2020 00:19:22

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 5'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:23:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '764d6e33-f641-43d9-8c3c-ac2f0f40eb47' User entered 'Yes (Y)'	System	15 Aug 2020 00:24:26
	System	15 Aug 2020 00:24:26

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:06', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '764d6e33-f641-43d9-8c3c-ac2f0f40eb47' User entered '97.9'	System	15 Aug 2020 00:24:26
	System	15 Aug 2020 00:24:26

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:11', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '764d6e33-f641-43d9-8c3c-ac2f0f40eb47'	System	15 Aug 2020 00:24:26
User entered 'No (N)'	System	15 Aug 2020 00:24:26

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:18', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '764d6e33-f641-43d9-8c3c-ac2f0f40eb47'	System	15 Aug 2020 00:24:26
User entered '14 Aug 2020 20:24'	System	15 Aug 2020 00:24:26

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 6'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:33:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1428018f-eb87-46e9-8aeb-0f5f45f8bf0f' User entered 'Yes (Y)'	System	15 Aug 2020 22:34:16
	System	15 Aug 2020 22:34:16

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:00', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1428018f-eb87-46e9-8aeb-0f5f45f8bf0f' User entered '98.1'	System	15 Aug 2020 22:34:16
	System	15 Aug 2020 22:34:16

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:06', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1428018f-eb87-46e9-8aeb-0f5f45f8bf0f'	System	15 Aug 2020 22:34:16
User entered 'No (N)'	System	15 Aug 2020 22:34:16

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:12', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1428018f-eb87-46e9-8aeb-0f5f45f8bf0f' User entered '15 Aug 2020 18:34'	System	15 Aug 2020 22:34:16
	System	15 Aug 2020 22:34:16

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 7'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:22:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '227269ae-9a58-44d7-8cd1-9481ba5f01f7' User entered 'Yes (Y)'	System	16 Aug 2020 23:23:00
	System	16 Aug 2020 23:23:00

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:22:47', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '227269ae-9a58-44d7-8cd1-9481ba5f01f7' User entered '98.0'	System	16 Aug 2020 23:23:00
	System	16 Aug 2020 23:23:00

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:22:53', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '227269ae-9a58-44d7-8cd1-9481ba5f01f7'	System	16 Aug 2020 23:23:00
User entered 'No (N)'	System	16 Aug 2020 23:23:00

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:22:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '227269ae-9a58-44d7-8cd1-9481ba5f01f7' User entered '16 Aug 2020 19:22'	System	16 Aug 2020 23:23:00
	System	16 Aug 2020 23:23:00

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:02:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ed33db8f-967b-4822-a35d-f8ab6114b6c1' User entered 'None (1)'	System	10 Aug 2020 23:03:18
	System	10 Aug 2020 23:03:18

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:02:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ed33db8f-967b-4822-a35d-f8ab6114b6c1' User entered 'No (N)'	System	10 Aug 2020 23:03:18
	System	10 Aug 2020 23:03:18

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ed33db8f-967b-4822-a35d-f8ab6114b6c1' User entered 'No (N)'	System	10 Aug 2020 23:03:18
	System	10 Aug 2020 23:03:18

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:10', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ed33db8f-967b-4822-a35d-f8ab6114b6c1' User entered 'None (1)'	System	10 Aug 2020 23:03:18
	System	10 Aug 2020 23:03:18

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:14', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ed33db8f-967b-4822-a35d-f8ab6114b6c1' User entered '10 Aug 2020 19:03'	System	10 Aug 2020 23:03:18
	System	10 Aug 2020 23:03:18

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 18:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 21:29'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 22:24'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 2'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:24:31', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b6b37b10-39a2-4138-b2ee-7fb3bb464107'	System	12 Aug 2020 00:28:41
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 00:28:41

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:24:39', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b6b37b10-39a2-4138-b2ee-7fb3bb464107' User entered 'No (N)'	System	12 Aug 2020 00:28:41
	System	12 Aug 2020 00:28:41

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:24:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b6b37b10-39a2-4138-b2ee-7fb3bb464107'	System	12 Aug 2020 00:28:41
User entered 'Yes (Y)'	System	12 Aug 2020 00:28:41

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'After talking with patient, it is a Grade 0'.	douglas winter (b) (4)	27 Sep 2020 16:00:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:27:47', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b6b37b10-39a2-4138-b2ee-7fb3bb464107'	System	12 Aug 2020 00:28:41
User entered '2'	System	12 Aug 2020 00:28:41

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:28:17', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b6b37b10-39a2-4138-b2ee-7fb3bb464107'	System	12 Aug 2020 00:28:41
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 00:28:41

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:28:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b6b37b10-39a2-4138-b2ee-7fb3bb464107' User entered '11 Aug 2020 20:28'	System	12 Aug 2020 00:28:41
	System	12 Aug 2020 00:28:41

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 3'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:02:16', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3dad38fe-825b-41f7-b663-2e4876a1deb3'	System	13 Aug 2020 00:03:51
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 00:03:51

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:02:23', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3dad38fe-825b-41f7-b663-2e4876a1deb3' User entered 'No (N)'	System	13 Aug 2020 00:03:51
	System	13 Aug 2020 00:03:51

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:02:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3dad38fe-825b-41f7-b663-2e4876a1deb3' User entered 'No (N)'	System	13 Aug 2020 00:03:51
	System	13 Aug 2020 00:03:51

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:03:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3dad38fe-825b-41f7-b663-2e4876a1deb3' User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 00:03:51
	System	13 Aug 2020 00:03:51

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:03:47', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3dad38fe-825b-41f7-b663-2e4876a1deb3' User entered '12 Aug 2020 20:03'	System	13 Aug 2020 00:03:51
	System	13 Aug 2020 00:03:51

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 4'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:19:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '803bb8c0-6789-458d-8e22-1ebf2e98aec9' User entered 'None (1)'	System	14 Aug 2020 00:20:08
	System	14 Aug 2020 00:20:08

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:19:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '803bb8c0-6789-458d-8e22-1ebf2e98aec9' User entered 'No (N)'	System	14 Aug 2020 00:20:08
	System	14 Aug 2020 00:20:08

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:19:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '803bb8c0-6789-458d-8e22-1ebf2e98aec9' User entered 'No (N)'	System	14 Aug 2020 00:20:08
	System	14 Aug 2020 00:20:08

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:03', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '803bb8c0-6789-458d-8e22-1ebf2e98aec9' User entered 'None (1)'	System	14 Aug 2020 00:20:08
	System	14 Aug 2020 00:20:08

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:07', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '803bb8c0-6789-458d-8e22-1ebf2e98aec9'	System	14 Aug 2020 00:20:08
User entered '13 Aug 2020 20:20'	System	14 Aug 2020 00:20:08

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 5'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1f23ccd8-7665-4803-afb2-396ee55217bb' User entered 'None (1)'	System	15 Aug 2020 00:24:49
	System	15 Aug 2020 00:24:49

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1f23ccd8-7665-4803-afb2-396ee55217bb' User entered 'No (N)'	System	15 Aug 2020 00:24:49
	System	15 Aug 2020 00:24:49

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1f23ccd8-7665-4803-afb2-396ee55217bb' User entered 'No (N)'	System	15 Aug 2020 00:24:49
	System	15 Aug 2020 00:24:49

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:44', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1f23ccd8-7665-4803-afb2-396ee55217bb' User entered 'None (1)'	System	15 Aug 2020 00:24:49
	System	15 Aug 2020 00:24:49

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:48', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1f23ccd8-7665-4803-afb2-396ee55217bb' User entered '14 Aug 2020 20:24'	System	15 Aug 2020 00:24:49
	System	15 Aug 2020 00:24:49

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 6'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:21', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '47278bb6-7b62-43c2-baed-690dc6f61aec' User entered 'None (1)'	System	15 Aug 2020 22:34:48
	System	15 Aug 2020 22:34:48

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:26', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '47278bb6-7b62-43c2-baed-690dc6f61aec' User entered 'No (N)'	System	15 Aug 2020 22:34:48
	System	15 Aug 2020 22:34:48

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:31', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '47278bb6-7b62-43c2-baed-690dc6f61aec' User entered 'No (N)'	System	15 Aug 2020 22:34:48
	System	15 Aug 2020 22:34:48

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '47278bb6-7b62-43c2-baed-690dc6f61aec' User entered 'None (1)'	System	15 Aug 2020 22:34:48
	System	15 Aug 2020 22:34:48

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '47278bb6-7b62-43c2-baed-690dc6f61aec' User entered '15 Aug 2020 18:34'	System	15 Aug 2020 22:34:48
	System	15 Aug 2020 22:34:48

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 7'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:09', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2c9c44fa-f886-4f2d-9cff-c13c575ae21e'	System	16 Aug 2020 23:23:29
User entered 'None (1)'	System	16 Aug 2020 23:23:29

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:15', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2c9c44fa-f886-4f2d-9cff-c13c575ae21e'	System	16 Aug 2020 23:23:29
User entered 'No (N)'	System	16 Aug 2020 23:23:29

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:19', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2c9c44fa-f886-4f2d-9cff-c13c575ae21e' User entered 'No (N)'	System	16 Aug 2020 23:23:29
	System	16 Aug 2020 23:23:29

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:23', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2c9c44fa-f886-4f2d-9cff-c13c575ae21e'	System	16 Aug 2020 23:23:29
User entered 'None (1)'	System	16 Aug 2020 23:23:29

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:27', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2c9c44fa-f886-4f2d-9cff-c13c575ae21e' User entered '16 Aug 2020 19:23'	System	16 Aug 2020 23:23:29
	System	16 Aug 2020 23:23:29

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:23', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd1e6db6d-4b48-4de1-91cb-22279c812a61' User entered 'None (0)'	System	10 Aug 2020 23:03:53
	System	10 Aug 2020 23:03:53

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:26', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd1e6db6d-4b48-4de1-91cb-22279c812a61' User entered 'None (0)'	System	10 Aug 2020 23:03:53
	System	10 Aug 2020 23:03:53

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd1e6db6d-4b48-4de1-91cb-22279c812a61' User entered 'None (0)'	System	10 Aug 2020 23:03:53
	System	10 Aug 2020 23:03:53

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd1e6db6d-4b48-4de1-91cb-22279c812a61' User entered 'None (0)'	System	10 Aug 2020 23:03:53
	System	10 Aug 2020 23:03:53

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd1e6db6d-4b48-4de1-91cb-22279c812a61' User entered 'None (0)'	System	10 Aug 2020 23:03:53
	System	10 Aug 2020 23:03:53

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd1e6db6d-4b48-4de1-91cb-22279c812a61' User entered 'None (0)'	System	10 Aug 2020 23:03:53
	System	10 Aug 2020 23:03:53

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd1e6db6d-4b48-4de1-91cb-22279c812a61'	System	10 Aug 2020 23:03:53
User entered 'No (N)'	System	10 Aug 2020 23:03:53

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-10T19:03:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd1e6db6d-4b48-4de1-91cb-22279c812a61' User entered '10 Aug 2020 19:03'	System	10 Aug 2020 23:03:53
	System	10 Aug 2020 23:03:53

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 18:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 21:29'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Aug 2020 22:24'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 2'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:23:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1c437855-18c9-4b18-98b9-c44a4528a194' User entered 'None (0)'	System	12 Aug 2020 00:24:17
	System	12 Aug 2020 00:24:17

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:23:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1c437855-18c9-4b18-98b9-c44a4528a194' User entered 'None (0)'	System	12 Aug 2020 00:24:17
	System	12 Aug 2020 00:24:17

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:23:45', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1c437855-18c9-4b18-98b9-c44a4528a194' User entered 'None (0)'	System	12 Aug 2020 00:24:17
	System	12 Aug 2020 00:24:17

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:23:50', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1c437855-18c9-4b18-98b9-c44a4528a194' User entered 'None (0)'	System	12 Aug 2020 00:24:17
	System	12 Aug 2020 00:24:17

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:23:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1c437855-18c9-4b18-98b9-c44a4528a194' User entered 'None (0)'	System	12 Aug 2020 00:24:17
	System	12 Aug 2020 00:24:17

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:23:57', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1c437855-18c9-4b18-98b9-c44a4528a194' User entered 'None (0)'	System	12 Aug 2020 00:24:17
	System	12 Aug 2020 00:24:17

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:24:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1c437855-18c9-4b18-98b9-c44a4528a194'	System	12 Aug 2020 00:24:17
User entered 'No (N)'	System	12 Aug 2020 00:24:17

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-11T20:24:13', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1c437855-18c9-4b18-98b9-c44a4528a194'	System	12 Aug 2020 00:24:17
User entered '11 Aug 2020 20:24'	System	12 Aug 2020 00:24:17

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 3'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:03:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5504ac0-be14-4678-b051-59ac14837366' User entered 'None (0)'	System	13 Aug 2020 00:04:37
	System	13 Aug 2020 00:04:37

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:04:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5504ac0-be14-4678-b051-59ac14837366' User entered 'None (0)'	System	13 Aug 2020 00:04:37
	System	13 Aug 2020 00:04:37

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:04:11', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5504ac0-be14-4678-b051-59ac14837366' User entered 'None (0)'	System	13 Aug 2020 00:04:37
	System	13 Aug 2020 00:04:37

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:04:15', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5504ac0-be14-4678-b051-59ac14837366' User entered 'None (0)'	System	13 Aug 2020 00:04:37
	System	13 Aug 2020 00:04:37

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:04:18', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5504ac0-be14-4678-b051-59ac14837366' User entered 'None (0)'	System	13 Aug 2020 00:04:37
	System	13 Aug 2020 00:04:37

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:04:21', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5504ac0-be14-4678-b051-59ac14837366' User entered 'None (0)'	System	13 Aug 2020 00:04:37
	System	13 Aug 2020 00:04:37

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:04:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5504ac0-be14-4678-b051-59ac14837366' User entered 'No (N)'	System	13 Aug 2020 00:04:37
	System	13 Aug 2020 00:04:37

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-12T20:04:36', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5504ac0-be14-4678-b051-59ac14837366' User entered '12 Aug 2020 20:04'	System	13 Aug 2020 00:04:37
	System	13 Aug 2020 00:04:37

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 4'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:13', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a90d2949-b97e-46cc-8b7e-2537e22d9607' User entered 'None (0)'	System	14 Aug 2020 00:20:38
	System	14 Aug 2020 00:20:38

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:16', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a90d2949-b97e-46cc-8b7e-2537e22d9607' User entered 'None (0)'	System	14 Aug 2020 00:20:38
	System	14 Aug 2020 00:20:38

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:19', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a90d2949-b97e-46cc-8b7e-2537e22d9607' User entered 'None (0)'	System	14 Aug 2020 00:20:38
	System	14 Aug 2020 00:20:38

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:22', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a90d2949-b97e-46cc-8b7e-2537e22d9607' User entered 'None (0)'	System	14 Aug 2020 00:20:38
	System	14 Aug 2020 00:20:38

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a90d2949-b97e-46cc-8b7e-2537e22d9607' User entered 'None (0)'	System	14 Aug 2020 00:20:38
	System	14 Aug 2020 00:20:38

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:27', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a90d2949-b97e-46cc-8b7e-2537e22d9607' User entered 'None (0)'	System	14 Aug 2020 00:20:38
	System	14 Aug 2020 00:20:38

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:33', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a90d2949-b97e-46cc-8b7e-2537e22d9607'	System	14 Aug 2020 00:20:38
User entered 'No (N)'	System	14 Aug 2020 00:20:38

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-13T20:20:36', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a90d2949-b97e-46cc-8b7e-2537e22d9607'	System	14 Aug 2020 00:20:38
User entered '13 Aug 2020 20:20'	System	14 Aug 2020 00:20:38

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 5'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd0f31f22-77bd-41c9-9ee0-8f22d0cff793' User entered 'None (0)'	System	15 Aug 2020 00:25:24
	System	15 Aug 2020 00:25:24

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:24:58', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd0f31f22-77bd-41c9-9ee0-8f22d0cff793' User entered 'None (0)'	System	15 Aug 2020 00:25:24
	System	15 Aug 2020 00:25:24

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:25:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd0f31f22-77bd-41c9-9ee0-8f22d0cff793' User entered 'None (0)'	System	15 Aug 2020 00:25:24
	System	15 Aug 2020 00:25:24

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:25:04', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd0f31f22-77bd-41c9-9ee0-8f22d0cff793' User entered 'None (0)'	System	15 Aug 2020 00:25:24
	System	15 Aug 2020 00:25:24

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:25:07', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd0f31f22-77bd-41c9-9ee0-8f22d0cff793' User entered 'None (0)'	System	15 Aug 2020 00:25:24
	System	15 Aug 2020 00:25:24

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:25:10', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd0f31f22-77bd-41c9-9ee0-8f22d0cff793' User entered 'None (0)'	System	15 Aug 2020 00:25:24
	System	15 Aug 2020 00:25:24

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:25:16', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd0f31f22-77bd-41c9-9ee0-8f22d0cff793'	System	15 Aug 2020 00:25:24
User entered 'No (N)'	System	15 Aug 2020 00:25:24

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-14T20:25:23', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd0f31f22-77bd-41c9-9ee0-8f22d0cff793'	System	15 Aug 2020 00:25:24
User entered '14 Aug 2020 20:25'	System	15 Aug 2020 00:25:24

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 6'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:34:53', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf753cca-8f31-41e2-9369-ff5431fa4088' User entered 'None (0)'	System	15 Aug 2020 22:35:34
	System	15 Aug 2020 22:35:34

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:35:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf753cca-8f31-41e2-9369-ff5431fa4088' User entered 'None (0)'	System	15 Aug 2020 22:35:34
	System	15 Aug 2020 22:35:34

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:35:08', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf753cca-8f31-41e2-9369-ff5431fa4088' User entered 'None (0)'	System	15 Aug 2020 22:35:34
	System	15 Aug 2020 22:35:34

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:35:12', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf753cca-8f31-41e2-9369-ff5431fa4088' User entered 'None (0)'	System	15 Aug 2020 22:35:34
	System	15 Aug 2020 22:35:34

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:35:15', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf753cca-8f31-41e2-9369-ff5431fa4088' User entered 'None (0)'	System	15 Aug 2020 22:35:34
	System	15 Aug 2020 22:35:34

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:35:18', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf753cca-8f31-41e2-9369-ff5431fa4088' User entered 'None (0)'	System	15 Aug 2020 22:35:34
	System	15 Aug 2020 22:35:34

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:35:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf753cca-8f31-41e2-9369-ff5431fa4088'	System	15 Aug 2020 22:35:34
User entered 'No (N)'	System	15 Aug 2020 22:35:34

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-15T18:35:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf753cca-8f31-41e2-9369-ff5431fa4088' User entered '15 Aug 2020 18:35'	System	15 Aug 2020 22:35:34
	System	15 Aug 2020 22:35:34

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 7'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:33', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e4ba2ee7-5384-4ee3-adc4-f142194b7e46' User entered 'None (0)'	System	16 Aug 2020 23:24:05
	System	16 Aug 2020 23:24:05

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e4ba2ee7-5384-4ee3-adc4-f142194b7e46' User entered 'None (0)'	System	16 Aug 2020 23:24:05
	System	16 Aug 2020 23:24:05

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e4ba2ee7-5384-4ee3-adc4-f142194b7e46' User entered 'None (0)'	System	16 Aug 2020 23:24:05
	System	16 Aug 2020 23:24:05

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:43', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e4ba2ee7-5384-4ee3-adc4-f142194b7e46' User entered 'None (0)'	System	16 Aug 2020 23:24:05
	System	16 Aug 2020 23:24:05

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e4ba2ee7-5384-4ee3-adc4-f142194b7e46' User entered 'None (0)'	System	16 Aug 2020 23:24:05
	System	16 Aug 2020 23:24:05

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e4ba2ee7-5384-4ee3-adc4-f142194b7e46' User entered 'None (0)'	System	16 Aug 2020 23:24:05
	System	16 Aug 2020 23:24:05

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:23:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e4ba2ee7-5384-4ee3-adc4-f142194b7e46' User entered 'No (N)'	System	16 Aug 2020 23:24:05
	System	16 Aug 2020 23:24:05

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-08-16T19:24:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e4ba2ee7-5384-4ee3-adc4-f142194b7e46' User entered '16 Aug 2020 19:24'	System	16 Aug 2020 23:24:05
	System	16 Aug 2020 23:24:05

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 22:42:55

US3222077

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:47:23

US3222077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '17 Aug 2020'	Jennifer Dittman (b) (4)	09 Sep 2020 21:47:23

US3222077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:47:23

US3222077

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	09 Sep 2020 21:47:23

US3222077

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:47:28

US3222077

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	09 Sep 2020 21:47:28

US3222077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:26

US3222077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:41:30
User entered '24 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	09 Sep 2020 21:48:26

US3222077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:26

US3222077

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:26

US3222077

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:31

US3222077

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	09 Sep 2020 21:48:31

US3222077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:46

US3222077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '3 Sep 2020'	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:46

US3222077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:46

US3222077

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:46

US3222077

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:48:51

US3222077

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	09 Sep 2020 21:48:51

US3222077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:01

US3222077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '9 Sep 2020'	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:01

US3222077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:01

US3222077

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'VISIT2'	System	09 Sep 2020 21:49:01

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '9 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '16:16'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '9 Sep 2020 16:16'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '37.0' C	Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '88'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'bpm'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '18'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'breaths/min'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '148'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'mmHg'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '97'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'mmHg'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '9 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '17:48'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '9 Sep 2020 17:48'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '98.8' F	Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '73'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'bpm'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '16'	Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'breaths/min'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '150'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'mmHg'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '99'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'mmHg'	System	10 Sep 2020 15:06:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:03:34

US3222077

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '9 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:03:34

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '9 Sep 2020'	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '17:18'	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '9 Sep 2020 17:18'	System	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'ONCE'	System	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:06:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 21:49:29

US3222077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:04:48

US3222077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '9 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:04:48

US3222077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '16:40'	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:04:48

US3222077

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '9 Sep 2020 16:40'	System	10 Sep 2020 15:04:48

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:06:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '9 Sep 2020'	Amber Vasquez (b) (4)	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '16:41'	Amber Vasquez (b) (4)	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:06:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '9 Sep 2020 16:41'	System	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4)	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Amber Vasquez (b) (4) (b) (4)	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:06:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered empty.	System	10 Sep 2020 15:05:04

US3222077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	09 Sep 2020 21:49:36

US3222077

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	09 Sep 2020 21:49:36

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:03:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1521b5da-d199-44fd-98d5-21c6b3ed5ecf' User entered 'Yes (Y)'	System	09 Sep 2020 23:03:57
	System	09 Sep 2020 23:03:57

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:03:43', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1521b5da-d199-44fd-98d5-21c6b3ed5ecf' User entered '98.5'	System	09 Sep 2020 23:03:57
	System	09 Sep 2020 23:03:57

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:03:50', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1521b5da-d199-44fd-98d5-21c6b3ed5ecf' User entered 'No (N)'	System	09 Sep 2020 23:03:57
	System	09 Sep 2020 23:03:57

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:03:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1521b5da-d199-44fd-98d5-21c6b3ed5ecf' User entered '09 Sep 2020 19:03'	System	09 Sep 2020 23:03:57
	System	09 Sep 2020 23:03:57

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 17:38'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 20:08'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 21:03'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 2'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:51:21', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf11418a-f869-4e74-9604-a7a32317f6c1' User entered 'Yes (Y)'	System	10 Sep 2020 22:51:42
	System	10 Sep 2020 22:51:42

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:51:26', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf11418a-f869-4e74-9604-a7a32317f6c1' User entered '98.5'	System	10 Sep 2020 22:51:42
	System	10 Sep 2020 22:51:42

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:51:33', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf11418a-f869-4e74-9604-a7a32317f6c1' User entered 'No (N)'	System	10 Sep 2020 22:51:42
	System	10 Sep 2020 22:51:42

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:51:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bf11418a-f869-4e74-9604-a7a32317f6c1' User entered '10 Sep 2020 18:51'	System	10 Sep 2020 22:51:42
	System	10 Sep 2020 22:51:42

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 3'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:38:08', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '58887512-74ba-43f9-bcb4-5aed770552c5' User entered 'Yes (Y)'	System	11 Sep 2020 23:39:51
	System	11 Sep 2020 23:39:51

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:39:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '58887512-74ba-43f9-bcb4-5aed770552c5' User entered '98.1'	System	11 Sep 2020 23:39:51
	System	11 Sep 2020 23:39:51

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:39:43', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '58887512-74ba-43f9-bcb4-5aed770552c5' User entered 'No (N)'	System	11 Sep 2020 23:39:51
	System	11 Sep 2020 23:39:51

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:39:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '58887512-74ba-43f9-bcb4-5aed770552c5' User entered '11 Sep 2020 19:39'	System	11 Sep 2020 23:39:51
	System	11 Sep 2020 23:39:51

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 4'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:53:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '74dfbd0f-d815-4b03-b9b4-04ef02697bff' User entered 'Yes (Y)'	System	12 Sep 2020 22:55:27
	System	12 Sep 2020 22:55:27

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:54:51', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '74dfbd0f-d815-4b03-b9b4-04ef02697bff' User entered '98.2'	System	12 Sep 2020 22:55:27
	System	12 Sep 2020 22:55:27

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:54:57', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '74dfbd0f-d815-4b03-b9b4-04ef02697bff'	System	12 Sep 2020 22:55:27
User entered 'No (N)'	System	12 Sep 2020 22:55:27

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:55:00', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '74dfbd0f-d815-4b03-b9b4-04ef02697bff' User entered '12 Sep 2020 18:55'	System	12 Sep 2020 22:55:27
	System	12 Sep 2020 22:55:27

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 5'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:20:15', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b93a62b1-d0b5-4ce7-88b3-f11cc871f40b' User entered 'Yes (Y)'	System	13 Sep 2020 23:20:35
	System	13 Sep 2020 23:20:35

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:20:22', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b93a62b1-d0b5-4ce7-88b3-f11cc871f40b' User entered '98.6'	System	13 Sep 2020 23:20:35
	System	13 Sep 2020 23:20:35

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:20:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b93a62b1-d0b5-4ce7-88b3-f11cc871f40b' User entered 'No (N)'	System	13 Sep 2020 23:20:35
	System	13 Sep 2020 23:20:35

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:20:33', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b93a62b1-d0b5-4ce7-88b3-f11cc871f40b' User entered '13 Sep 2020 19:20'	System	13 Sep 2020 23:20:35
	System	13 Sep 2020 23:20:35

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 6'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:35:55', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b2797934-d047-432b-a9d2-1c438bf15d45'	System	14 Sep 2020 23:36:28
User entered 'Yes (Y)'	System	14 Sep 2020 23:36:28

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:17', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b2797934-d047-432b-a9d2-1c438bf15d45'	System	14 Sep 2020 23:36:28
User entered '98.4'	System	14 Sep 2020 23:36:28

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b2797934-d047-432b-a9d2-1c438bf15d45'	System	14 Sep 2020 23:36:28
User entered 'No (N)'	System	14 Sep 2020 23:36:28

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b2797934-d047-432b-a9d2-1c438bf15d45'	System	14 Sep 2020 23:36:28
User entered '14 Sep 2020 19:36'	System	14 Sep 2020 23:36:28

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 7'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:30:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '851f8a42-5d3a-41ff-b83b-6f788e53d6fd' User entered 'Yes (Y)'	System	16 Sep 2020 00:30:57
	System	16 Sep 2020 00:30:57

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:30:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '851f8a42-5d3a-41ff-b83b-6f788e53d6fd' User entered '98.3'	System	16 Sep 2020 00:30:57
	System	16 Sep 2020 00:30:57

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:30:48', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '851f8a42-5d3a-41ff-b83b-6f788e53d6fd' User entered 'No (N)'	System	16 Sep 2020 00:30:57
	System	16 Sep 2020 00:30:57

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:30:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '851f8a42-5d3a-41ff-b83b-6f788e53d6fd' User entered '15 Sep 2020 20:30'	System	16 Sep 2020 00:30:57
	System	16 Sep 2020 00:30:57

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b16e940b-7508-42b1-a4c1-6f6d620cfd1d' User entered 'None (1)'	System	09 Sep 2020 23:04:41
	System	09 Sep 2020 23:04:41

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:22', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b16e940b-7508-42b1-a4c1-6f6d620cfd1d' User entered 'No (N)'	System	09 Sep 2020 23:04:41
	System	09 Sep 2020 23:04:41

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:27', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b16e940b-7508-42b1-a4c1-6f6d620cfd1d' User entered 'No (N)'	System	09 Sep 2020 23:04:41
	System	09 Sep 2020 23:04:41

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b16e940b-7508-42b1-a4c1-6f6d620cfd1d' User entered 'None (1)'	System	09 Sep 2020 23:04:41
	System	09 Sep 2020 23:04:41

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b16e940b-7508-42b1-a4c1-6f6d620cfd1d' User entered '09 Sep 2020 19:04'	System	09 Sep 2020 23:04:41
	System	09 Sep 2020 23:04:41

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 17:38'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 20:08'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 21:03'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 2'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:52:06', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5a42243-8941-4137-b447-4f84b196f475'	System	10 Sep 2020 22:55:19
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 22:55:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:52:27', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5a42243-8941-4137-b447-4f84b196f475' User entered 'No (N)'	System	10 Sep 2020 22:55:19
	System	10 Sep 2020 22:55:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:54:11', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5a42243-8941-4137-b447-4f84b196f475' User entered 'Yes (Y)'	System	10 Sep 2020 22:55:19
	System	10 Sep 2020 22:55:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:54:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5a42243-8941-4137-b447-4f84b196f475' User entered '8'	System	10 Sep 2020 22:55:19
	System	10 Sep 2020 22:55:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:07', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5a42243-8941-4137-b447-4f84b196f475'	System	10 Sep 2020 22:55:19
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 22:55:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:17', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f5a42243-8941-4137-b447-4f84b196f475'	System	10 Sep 2020 22:55:19
User entered '10 Sep 2020 18:55'	System	10 Sep 2020 22:55:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 3'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:40:10', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fbf63ee4-30f6-4e16-83c2-612fbd1c437b' User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 23:40:59
	System	11 Sep 2020 23:40:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:40:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fbf63ee4-30f6-4e16-83c2-612fbd1c437b' User entered 'No (N)'	System	11 Sep 2020 23:40:59
	System	11 Sep 2020 23:40:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:40:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fbf63ee4-30f6-4e16-83c2-612fbd1c437b' User entered 'Yes (Y)'	System	11 Sep 2020 23:40:59
	System	11 Sep 2020 23:40:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:40:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fbf63ee4-30f6-4e16-83c2-612fbd1c437b' User entered '5'	System	11 Sep 2020 23:40:59
	System	11 Sep 2020 23:40:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:40:51', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fbf63ee4-30f6-4e16-83c2-612fbd1c437b' User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 23:40:59
	System	11 Sep 2020 23:40:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:40:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fbf63ee4-30f6-4e16-83c2-612fbd1c437b' User entered '11 Sep 2020 19:40'	System	11 Sep 2020 23:40:59
	System	11 Sep 2020 23:40:59

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 4'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:08', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8abe6385-27b6-4b22-9267-7103120b94d0'	System	12 Sep 2020 22:52:47
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 22:52:47

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:16', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8abe6385-27b6-4b22-9267-7103120b94d0' User entered 'No (N)'	System	12 Sep 2020 22:52:47
	System	12 Sep 2020 22:52:47

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8abe6385-27b6-4b22-9267-7103120b94d0' User entered 'Yes (Y)'	System	12 Sep 2020 22:52:47
	System	12 Sep 2020 22:52:47

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8abe6385-27b6-4b22-9267-7103120b94d0' User entered '6'	System	12 Sep 2020 22:52:47
	System	12 Sep 2020 22:52:47

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:36', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8abe6385-27b6-4b22-9267-7103120b94d0'	System	12 Sep 2020 22:52:47
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 22:52:47

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8abe6385-27b6-4b22-9267-7103120b94d0' User entered '12 Sep 2020 18:52'	System	12 Sep 2020 22:52:47
	System	12 Sep 2020 22:52:47

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 5'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:20:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e3d74dcb-386f-4d82-ac49-d32299fffde0'	System	13 Sep 2020 23:21:42
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 23:21:42

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:20:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e3d74dcb-386f-4d82-ac49-d32299fffd0'	System	13 Sep 2020 23:21:42
User entered 'No (N)'	System	13 Sep 2020 23:21:42

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:20:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e3d74dcb-386f-4d82-ac49-d32299fffde0' User entered 'Yes (Y)'	System	13 Sep 2020 23:21:42
	System	13 Sep 2020 23:21:42

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:20:52', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e3d74dcb-386f-4d82-ac49-d32299ffde0' User entered '6'	System	13 Sep 2020 23:21:42
	System	13 Sep 2020 23:21:42

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:21:27', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e3d74dcb-386f-4d82-ac49-d32299fffde0' User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 23:21:42
	System	13 Sep 2020 23:21:42

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:21:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e3d74dcb-386f-4d82-ac49-d32299ffde0' User entered '13 Sep 2020 19:21'	System	13 Sep 2020 23:21:42
	System	13 Sep 2020 23:21:42

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 6'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:35:09', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7e669987-c081-43c2-8f79-e363d1ee5aa3'	System	14 Sep 2020 23:35:45
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:35:14', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7e669987-c081-43c2-8f79-e363d1ee5aa3' User entered 'No (N)'	System	14 Sep 2020 23:35:45
	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:35:17', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7e669987-c081-43c2-8f79-e363d1ee5aa3'	System	14 Sep 2020 23:35:45
User entered 'Yes (Y)'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:35:21', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7e669987-c081-43c2-8f79-e363d1ee5aa3'	System	14 Sep 2020 23:35:45
User entered '4'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:35:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7e669987-c081-43c2-8f79-e363d1ee5aa3'	System	14 Sep 2020 23:35:45
User entered 'None (1)'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:35:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7e669987-c081-43c2-8f79-e363d1ee5aa3' User entered '14 Sep 2020 19:35'	System	14 Sep 2020 23:35:45
	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 7'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:26:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2d01ea22-e5e3-4cc4-aa8c-93a6bea7b775' User entered 'None (1)'	System	16 Sep 2020 00:27:19
	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:26:43', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2d01ea22-e5e3-4cc4-aa8c-93a6bea7b775' User entered 'No (N)'	System	16 Sep 2020 00:27:19
	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:26:48', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2d01ea22-e5e3-4cc4-aa8c-93a6bea7b775' User entered 'Yes (Y)'	System	16 Sep 2020 00:27:19
	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:26:52', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2d01ea22-e5e3-4cc4-aa8c-93a6bea7b775' User entered '2'	System	16 Sep 2020 00:27:19
	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:27:13', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2d01ea22-e5e3-4cc4-aa8c-93a6bea7b775' User entered 'None (1)'	System	16 Sep 2020 00:27:19
	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:27:17', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2d01ea22-e5e3-4cc4-aa8c-93a6bea7b775' User entered '15 Sep 2020 20:27'	System	16 Sep 2020 00:27:19
	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:47', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc4d43ca-8995-47f3-974e-f52bd3c4acdc' User entered 'None (0)'	System	09 Sep 2020 23:06:22
	System	09 Sep 2020 23:06:22

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:51', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc4d43ca-8995-47f3-974e-f52bd3c4acdc' User entered 'None (0)'	System	09 Sep 2020 23:06:22
	System	09 Sep 2020 23:06:22

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc4d43ca-8995-47f3-974e-f52bd3c4acdc' User entered 'None (0)'	System	09 Sep 2020 23:06:22
	System	09 Sep 2020 23:06:22

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc4d43ca-8995-47f3-974e-f52bd3c4acdc' User entered 'None (0)'	System	09 Sep 2020 23:06:22
	System	09 Sep 2020 23:06:22

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:04:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc4d43ca-8995-47f3-974e-f52bd3c4acdc' User entered 'None (0)'	System	09 Sep 2020 23:06:22
	System	09 Sep 2020 23:06:22

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:05:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc4d43ca-8995-47f3-974e-f52bd3c4acdc' User entered 'None (0)'	System	09 Sep 2020 23:06:22
	System	09 Sep 2020 23:06:22

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:06:00', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc4d43ca-8995-47f3-974e-f52bd3c4acdc' User entered 'No (N)'	System	09 Sep 2020 23:06:22
	System	09 Sep 2020 23:06:22

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-09T19:06:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc4d43ca-8995-47f3-974e-f52bd3c4acdc' User entered '09 Sep 2020 19:06'	System	09 Sep 2020 23:06:22
	System	09 Sep 2020 23:06:22

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 17:38'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 20:08'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Sep 2020 21:03'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 2'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ffe8a61-81a3-47e1-9a72-c9b2dfa2f702'	System	10 Sep 2020 22:56:05
User entered 'None (0)'	System	10 Sep 2020 22:56:05

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:36', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ffe8a61-81a3-47e1-9a72-c9b2dfa2f702'	System	10 Sep 2020 22:56:05
User entered 'No interference with activity (1)'	System	10 Sep 2020 22:56:05

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:41', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ffe8a61-81a3-47e1-9a72-c9b2dfa2f702' User entered 'None (0)'	System	10 Sep 2020 22:56:05
	System	10 Sep 2020 22:56:05

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:45', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ffe8a61-81a3-47e1-9a72-c9b2dfa2f702' User entered 'None (0)'	System	10 Sep 2020 22:56:05
	System	10 Sep 2020 22:56:05

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ffe8a61-81a3-47e1-9a72-c9b2dfa2f702' User entered 'None (0)'	System	10 Sep 2020 22:56:05
	System	10 Sep 2020 22:56:05

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:51', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ffe8a61-81a3-47e1-9a72-c9b2dfa2f702'	System	10 Sep 2020 22:56:05
User entered 'None (0)'	System	10 Sep 2020 22:56:05

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:55:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ffe8a61-81a3-47e1-9a72-c9b2dfa2f702'	System	10 Sep 2020 22:56:05
User entered 'No (N)'	System	10 Sep 2020 22:56:05

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-10T18:56:02', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ffe8a61-81a3-47e1-9a72-c9b2dfa2f702'	System	10 Sep 2020 22:56:05
User entered '10 Sep 2020 18:56'	System	10 Sep 2020 22:56:05

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 3'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:41:04', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '28dd880b-b792-4308-9e10-b4678b023957' User entered 'None (0)'	System	11 Sep 2020 23:41:56
	System	11 Sep 2020 23:41:56

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:41:13', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '28dd880b-b792-4308-9e10-b4678b023957'	System	11 Sep 2020 23:41:56
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:41:56

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:41:18', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '28dd880b-b792-4308-9e10-b4678b023957'	System	11 Sep 2020 23:41:56
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:41:56

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:41:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '28dd880b-b792-4308-9e10-b4678b023957'	System	11 Sep 2020 23:41:56
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:41:56

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:41:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '28dd880b-b792-4308-9e10-b4678b023957' User entered 'None (0)'	System	11 Sep 2020 23:41:56
	System	11 Sep 2020 23:41:56

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:41:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '28dd880b-b792-4308-9e10-b4678b023957' User entered 'None (0)'	System	11 Sep 2020 23:41:56
	System	11 Sep 2020 23:41:56

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:41:50', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '28dd880b-b792-4308-9e10-b4678b023957'	System	11 Sep 2020 23:41:56
User entered 'No (N)'	System	11 Sep 2020 23:41:56

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-11T19:41:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '28dd880b-b792-4308-9e10-b4678b023957'	System	11 Sep 2020 23:41:56
User entered '11 Sep 2020 19:41'	System	11 Sep 2020 23:41:56

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 4'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e94a98b0-f38e-4ed7-91b6-9c899f907ee1' User entered 'None (0)'	System	12 Sep 2020 22:53:29
	System	12 Sep 2020 22:53:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e94a98b0-f38e-4ed7-91b6-9c899f907ee1'	System	12 Sep 2020 22:53:29
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:53:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:52:57', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e94a98b0-f38e-4ed7-91b6-9c899f907ee1' User entered 'No interference with activity (1)'	System	12 Sep 2020 22:53:29
	System	12 Sep 2020 22:53:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:53:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e94a98b0-f38e-4ed7-91b6-9c899f907ee1'	System	12 Sep 2020 22:53:29
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:53:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:53:08', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e94a98b0-f38e-4ed7-91b6-9c899f907ee1' User entered 'None (0)'	System	12 Sep 2020 22:53:29
	System	12 Sep 2020 22:53:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:53:11', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e94a98b0-f38e-4ed7-91b6-9c899f907ee1' User entered 'None (0)'	System	12 Sep 2020 22:53:29
	System	12 Sep 2020 22:53:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:53:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e94a98b0-f38e-4ed7-91b6-9c899f907ee1' User entered 'No (N)'	System	12 Sep 2020 22:53:29
	System	12 Sep 2020 22:53:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-12T18:53:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e94a98b0-f38e-4ed7-91b6-9c899f907ee1' User entered '12 Sep 2020 18:53'	System	12 Sep 2020 22:53:29
	System	12 Sep 2020 22:53:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 5'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:21:47', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'caa5acd9-f3d7-4aca-b220-59ec5f3802fa' User entered 'None (0)'	System	13 Sep 2020 23:22:10
	System	13 Sep 2020 23:22:10

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:21:50', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'caa5acd9-f3d7-4aca-b220-59ec5f3802fa'	System	13 Sep 2020 23:22:10
User entered 'No interference with activity (1)'	System	13 Sep 2020 23:22:10

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:21:53', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'caa5acd9-f3d7-4aca-b220-59ec5f3802fa' User entered 'No interference with activity (1)'	System	13 Sep 2020 23:22:10
	System	13 Sep 2020 23:22:10

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:21:55', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'caa5acd9-f3d7-4aca-b220-59ec5f3802fa' User entered 'No interference with activity (1)'	System	13 Sep 2020 23:22:10
	System	13 Sep 2020 23:22:10

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:21:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'caa5acd9-f3d7-4aca-b220-59ec5f3802fa' User entered 'None (0)'	System	13 Sep 2020 23:22:10
	System	13 Sep 2020 23:22:10

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:22:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'caa5acd9-f3d7-4aca-b220-59ec5f3802fa' User entered 'None (0)'	System	13 Sep 2020 23:22:10
	System	13 Sep 2020 23:22:10

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:22:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'caa5acd9-f3d7-4aca-b220-59ec5f3802fa' User entered 'No (N)'	System	13 Sep 2020 23:22:10
	System	13 Sep 2020 23:22:10

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-13T19:22:08', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'caa5acd9-f3d7-4aca-b220-59ec5f3802fa' User entered '13 Sep 2020 19:22'	System	13 Sep 2020 23:22:10
	System	13 Sep 2020 23:22:10

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 6'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f80165d-363f-42bf-a593-a1a5c2c7ae4e' User entered 'None (0)'	System	14 Sep 2020 23:37:00
	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f80165d-363f-42bf-a593-a1a5c2c7ae4e'	System	14 Sep 2020 23:37:00
User entered 'No interference with activity (1)'	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f80165d-363f-42bf-a593-a1a5c2c7ae4e' User entered 'No interference with activity (1)'	System	14 Sep 2020 23:37:00
	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:45', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f80165d-363f-42bf-a593-a1a5c2c7ae4e' User entered 'None (0)'	System	14 Sep 2020 23:37:00
	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:48', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f80165d-363f-42bf-a593-a1a5c2c7ae4e' User entered 'None (0)'	System	14 Sep 2020 23:37:00
	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:50', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f80165d-363f-42bf-a593-a1a5c2c7ae4e' User entered 'None (0)'	System	14 Sep 2020 23:37:00
	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:55', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f80165d-363f-42bf-a593-a1a5c2c7ae4e' User entered 'No (N)'	System	14 Sep 2020 23:37:00
	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-14T19:36:58', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f80165d-363f-42bf-a593-a1a5c2c7ae4e' User entered '14 Sep 2020 19:36'	System	14 Sep 2020 23:37:00
	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	09 Sep 2020 21:49:29
User entered 'Day 7'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:28:36', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a63a6297-a5a5-49be-8b89-f6b597d8ab5a'	System	16 Sep 2020 00:30:14
User entered 'No interference with activity (1)'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'The patient is passing a kidney stone and his fatigue is from that and not from the vaccine.'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:28:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:29:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a63a6297-a5a5-49be-8b89-f6b597d8ab5a'	System	16 Sep 2020 00:30:14
User entered 'Significant; prevents daily activity (3)'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'The patient is passing a kidney stone and muscle aches is from that and not from the vaccine.'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:28:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:29:12', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a63a6297-a5a5-49be-8b89-f6b597d8ab5a'	System	16 Sep 2020 00:30:14
User entered 'Some interference with activity (2)'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:29:19', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a63a6297-a5a5-49be-8b89-f6b597d8ab5a' User entered 'None (0)'	System	16 Sep 2020 00:30:14
	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'Patient has history of kidney stone and n/v is from that and the vaccine.'	douglas winter (b) (4)	27 Sep 2020 16:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:29:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a63a6297-a5a5-49be-8b89-f6b597d8ab5a'	System	16 Sep 2020 00:30:14
User entered 'Prevents daily activity, requires outpatient IV hydration (3)'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'The patient is passing a kidney stone and chills is from that and not from the vaccine.'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:27:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:29:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a63a6297-a5a5-49be-8b89-f6b597d8ab5a'	System	16 Sep 2020 00:30:14
User entered 'No interference with activity (1)'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:29:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a63a6297-a5a5-49be-8b89-f6b597d8ab5a' User entered 'Yes (Y)'	System	16 Sep 2020 00:30:14
	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-15T20:30:10', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a63a6297-a5a5-49be-8b89-f6b597d8ab5a' User entered '15 Sep 2020 20:30'	System	16 Sep 2020 00:30:14
	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 21:49:29

US3222077

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	14 Sep 2020 23:35:45
User entered 'Day 8'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:06:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:52:23', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '266ddb6a-da56-46d2-8d80-b089784e69ee' User entered 'No (N)'	System	16 Sep 2020 22:52:33
	System	16 Sep 2020 22:52:33

US3222077

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:52:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '266ddb6a-da56-46d2-8d80-b089784e69ee' User entered '16 Sep 2020 18:52'	System	16 Sep 2020 22:52:33
	System	16 Sep 2020 22:52:33

US3222077

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 00:30:14
User entered 'Day 8'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:49:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bfd1bf81-c579-4bfc-881b-af445cb555a7' User entered 'None (0)'	System	16 Sep 2020 22:49:50
	System	16 Sep 2020 22:49:50

US3222077

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:49:47', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bfd1bf81-c579-4bfc-881b-af445cb555a7' User entered '16 Sep 2020 18:49'	System	16 Sep 2020 22:49:50
	System	16 Sep 2020 22:49:50

US3222077

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	14 Sep 2020 23:37:00
User entered 'Day 8'	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:50:04', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a26de77d-adb4-43cc-ae9c-ba222a9f1609'	System	16 Sep 2020 22:50:17
User entered 'Significant; prevents daily activity (3)'	System	16 Sep 2020 22:50:17

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:50:11', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a26de77d-adb4-43cc-ae9c-ba222a9f1609'	System	16 Sep 2020 22:50:17
User entered '16 Sep 2020 18:50'	System	16 Sep 2020 22:50:17

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 00:30:14
User entered 'Day 9'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-17T19:30:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '66e03658-9c1a-4cd9-9f1a-649995b42260'	System	17 Sep 2020 23:30:40
User entered 'No interference with activity (1)'	System	17 Sep 2020 23:30:40

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-17T19:30:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '66e03658-9c1a-4cd9-9f1a-649995b42260' User entered '17 Sep 2020 19:30'	System	17 Sep 2020 23:30:40
	System	17 Sep 2020 23:30:40

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 22:50:17
User entered 'Day 10'	System	16 Sep 2020 22:50:17

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-18T20:20:15', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '59002c36-1e6e-47bf-9505-92dd5a84f945'	System	19 Sep 2020 00:20:21
User entered 'No interference with activity (1)'	System	19 Sep 2020 00:20:21

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-18T20:20:18', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '59002c36-1e6e-47bf-9505-92dd5a84f945'	System	19 Sep 2020 00:20:21
User entered '18 Sep 2020 20:20'	System	19 Sep 2020 00:20:21

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:50:17

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:50:17

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	17 Sep 2020 23:30:40
User entered 'Day 11'	System	17 Sep 2020 23:30:40

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T06:28:06', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ac6182b2-3cdc-442a-b55d-f61d22ea0718'	System	20 Sep 2020 10:28:13
User entered 'Some interference with activity (2)'	System	20 Sep 2020 10:28:13

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T06:28:10', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ac6182b2-3cdc-442a-b55d-f61d22ea0718' User entered '20 Sep 2020 06:28'	System	20 Sep 2020 10:28:13
	System	20 Sep 2020 10:28:13

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 23:30:40

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 23:30:40

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	19 Sep 2020 00:20:21
User entered 'Day 12'	System	19 Sep 2020 00:20:21

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T12:06:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '397bd4d2-279d-4f25-a7cc-e06ac1b3cb32'	System	20 Sep 2020 16:07:09
User entered 'Some interference with activity (2)'	System	20 Sep 2020 16:07:09

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T12:07:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '397bd4d2-279d-4f25-a7cc-e06ac1b3cb32' User entered '20 Sep 2020 12:07'	System	20 Sep 2020 16:07:09
	System	20 Sep 2020 16:07:09

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:20:21

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:20:21

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	20 Sep 2020 10:28:13
User entered 'Day 13'	System	20 Sep 2020 10:28:13

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-21T21:39:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '6032d6bd-a0be-4cf4-9a84-669b413a2569'	System	22 Sep 2020 01:39:49
User entered 'Some interference with activity (2)'	System	22 Sep 2020 01:39:49

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-21T21:39:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '6032d6bd-a0be-4cf4-9a84-669b413a2569' User entered '21 Sep 2020 21:39'	System	22 Sep 2020 01:39:49
	System	22 Sep 2020 01:39:49

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 10:28:13

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 10:28:13

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	20 Sep 2020 16:07:09
User entered 'Day 14'	System	20 Sep 2020 16:07:09

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-22T12:11:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5255fe3c-763b-4b19-a347-c90d8dfc234b' User entered 'Some interference with activity (2)'	System	22 Sep 2020 16:11:30
	System	22 Sep 2020 16:11:30

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-22T12:11:28', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5255fe3c-763b-4b19-a347-c90d8dfc234b' User entered '22 Sep 2020 12:11'	System	22 Sep 2020 16:11:30
	System	22 Sep 2020 16:11:30

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 16:07:09

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 16:07:09

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	22 Sep 2020 01:39:49
User entered 'Day 15'	System	22 Sep 2020 01:39:49

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-23T12:01:08', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '16fd1b4c-99fa-46ea-8199-9794faa918fe' User entered 'Significant; prevents daily activity (3)'	System	23 Sep 2020 16:01:53

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-23T12:01:11', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '16fd1b4c-99fa-46ea-8199-9794faa918fe' User entered '23 Sep 2020 12:01'	System	23 Sep 2020 16:01:53
	System	23 Sep 2020 16:01:53

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 01:39:49

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 01:39:49

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	22 Sep 2020 16:11:30
User entered 'Day 16'	System	22 Sep 2020 16:11:30

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-24T18:53:31', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cc7f41cb-55bc-47df-935d-6d2a1a4bfd90'	System	24 Sep 2020 22:53:37
User entered 'No interference with activity (1)'	System	24 Sep 2020 22:53:37

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-24T18:53:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cc7f41cb-55bc-47df-935d-6d2a1a4bfd90'	System	24 Sep 2020 22:53:37
User entered '24 Sep 2020 18:53'	System	24 Sep 2020 22:53:37

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:11:30

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:11:30

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	23 Sep 2020 16:01:53
User entered 'Day 17'	System	23 Sep 2020 16:01:53

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T09:35:45', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '0d8b510a-9666-4988-b57a-fd4ec961240a' User entered 'No interference with activity (1)'	System	26 Sep 2020 13:35:54
	System	26 Sep 2020 13:35:54

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T09:35:48', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '0d8b510a-9666-4988-b57a-fd4ec961240a' User entered '26 Sep 2020 09:35'	System	26 Sep 2020 13:35:54
	System	26 Sep 2020 13:35:54

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:01:53

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:01:53

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	24 Sep 2020 22:53:37
User entered 'Day 18'	System	24 Sep 2020 22:53:37

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T12:00:19', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '794215cd-27d3-44aa-9100-5722c4f63b7d'	System	26 Sep 2020 16:00:29
User entered 'No interference with activity (1)'	System	26 Sep 2020 16:00:29

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T12:00:23', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '794215cd-27d3-44aa-9100-5722c4f63b7d' User entered '26 Sep 2020 12:00'	System	26 Sep 2020 16:00:29
	System	26 Sep 2020 16:00:29

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 22:53:37

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 22:53:37

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	26 Sep 2020 13:35:54
User entered 'Day 19'	System	26 Sep 2020 13:35:54

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 13:35:54

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 13:35:54

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	26 Sep 2020 16:00:29
User entered 'Day 20'	System	26 Sep 2020 16:00:29

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-28T12:00:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '10ee532f-901c-48c4-a4c7-fe5123181a85'	System	28 Sep 2020 16:00:34
User entered 'Significant; prevents daily activity (3)'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-28T12:00:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '10ee532f-901c-48c4-a4c7-fe5123181a85'	System	28 Sep 2020 16:00:34
User entered '28 Sep 2020 12:00'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 16:00:29

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 16:00:29

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	28 Sep 2020 16:00:34
User entered 'Day 21'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-29T12:21:28', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7be25d2b-a4ef-4997-a7eb-613081197f73'	System	29 Sep 2020 16:21:43
User entered 'Significant; prevents daily activity (3)'	System	29 Sep 2020 16:21:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-29T12:21:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7be25d2b-a4ef-4997-a7eb-613081197f73' User entered '29 Sep 2020 12:21'	System	29 Sep 2020 16:21:43
	System	29 Sep 2020 16:21:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	28 Sep 2020 16:00:34
User entered 'Day 22'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-30T22:42:45', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '6639303d-146b-4fd1-9d35-5fa442023343' User entered 'Significant; prevents daily activity (3)'	System	01 Oct 2020 02:42:51
	System	01 Oct 2020 02:42:51

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-30T22:42:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '6639303d-146b-4fd1-9d35-5fa442023343' User entered '30 Sep 2020 22:42'	System	01 Oct 2020 02:42:51
	System	01 Oct 2020 02:42:51

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	29 Sep 2020 16:21:43
User entered 'Day 23'	System	29 Sep 2020 16:21:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-01T12:01:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '05ea4429-049b-416d-adb7-5ad16c426249' User entered 'Significant; prevents daily activity (3)'	System	01 Oct 2020 16:02:11
	System	01 Oct 2020 16:02:11

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-01T12:01:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '05ea4429-049b-416d-adb7-5ad16c426249' User entered '01 Oct 2020 12:01'	System	01 Oct 2020 16:02:11
	System	01 Oct 2020 16:02:11

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:21:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:21:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	01 Oct 2020 02:42:51
User entered 'Day 24'	System	01 Oct 2020 02:42:51

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-02T12:01:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f7141f7e-c64a-446c-a015-85e0c979b288' User entered 'Significant; prevents daily activity (3)'	System	02 Oct 2020 16:02:15

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-02T12:01:45', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f7141f7e-c64a-446c-a015-85e0c979b288' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 16:02:15
	System	02 Oct 2020 16:02:15

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 02:42:51

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 02:42:51

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	01 Oct 2020 16:02:11
User entered 'Day 25'	System	01 Oct 2020 16:02:11

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-03T12:00:19', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9e2ebc22-320c-4c22-8c34-8d98f26e99d8' User entered 'Significant; prevents daily activity (3)'	System	03 Oct 2020 16:00:27
	System	03 Oct 2020 16:00:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-03T12:00:22', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9e2ebc22-320c-4c22-8c34-8d98f26e99d8' User entered '03 Oct 2020 12:00'	System	03 Oct 2020 16:00:27
	System	03 Oct 2020 16:00:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:02:11

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:02:11

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	02 Oct 2020 16:02:15
User entered 'Day 26'	System	02 Oct 2020 16:02:15

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-04T12:00:17', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cc8fc3e0-77d2-4716-981b-61e2cecb97b3'	System	04 Oct 2020 16:00:24
User entered 'Significant; prevents daily activity (3)'	System	04 Oct 2020 16:00:24

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-04T12:00:21', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cc8fc3e0-77d2-4716-981b-61e2cecb97b3' User entered '04 Oct 2020 12:00'	System	04 Oct 2020 16:00:24
	System	04 Oct 2020 16:00:24

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 16:02:15

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 16:02:15

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	03 Oct 2020 16:00:27
User entered 'Day 27'	System	03 Oct 2020 16:00:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-05T22:38:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f6a9c87-f6eb-42f0-b073-9f9c7ed52bdc' User entered 'Significant; prevents daily activity (3)'	System	06 Oct 2020 02:38:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-05T22:38:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '9f6a9c87-f6eb-42f0-b073-9f9c7ed52bdc' User entered '05 Oct 2020 22:38'	System	06 Oct 2020 02:38:28
	System	06 Oct 2020 02:38:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 16:00:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 16:00:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	04 Oct 2020 16:00:24
User entered 'Day 28'	System	04 Oct 2020 16:00:24

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-06T12:05:45', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'eb37f54a-f24c-43fb-ba7d-f776d6745b81' User entered 'Some interference with activity (2)'	System	06 Oct 2020 16:05:52
	System	06 Oct 2020 16:05:52

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-06T12:05:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'eb37f54a-f24c-43fb-ba7d-f776d6745b81' User entered '06 Oct 2020 12:05'	System	06 Oct 2020 16:05:52
	System	06 Oct 2020 16:05:52

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 16:00:24

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 16:00:24

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	06 Oct 2020 02:38:28
User entered 'Day 29'	System	06 Oct 2020 02:38:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-07T17:21:23', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3a00841b-5af3-40a7-863e-fbc91e168504'	System	07 Oct 2020 21:21:27
User entered 'No interference with activity (1)'	System	07 Oct 2020 21:21:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-07T17:21:26', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3a00841b-5af3-40a7-863e-fbc91e168504' User entered '07 Oct 2020 17:21'	System	07 Oct 2020 21:21:27
	System	07 Oct 2020 21:21:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 02:38:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 02:38:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	06 Oct 2020 16:05:52
User entered 'Day 30'	System	06 Oct 2020 16:05:52

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-08T12:00:28', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5329ee39-8381-4738-854e-0750058e61aa'	System	08 Oct 2020 16:00:46
User entered 'No interference with activity (1)'	System	08 Oct 2020 16:00:46

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-08T12:00:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5329ee39-8381-4738-854e-0750058e61aa' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 16:00:46
	System	08 Oct 2020 16:00:46

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 16:05:52

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 16:05:52

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	07 Oct 2020 21:21:27
User entered 'Day 31'	System	07 Oct 2020 21:21:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-09T14:25:28', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8b632e36-f04b-48d6-81f3-ed8251bb547f' User entered 'Some interference with activity (2)'	System	11 Oct 2020 14:24:28
	System	11 Oct 2020 14:24:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-09T14:25:31', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8b632e36-f04b-48d6-81f3-ed8251bb547f' User entered '09 Oct 2020 14:25'	System	11 Oct 2020 14:24:28
	System	11 Oct 2020 14:24:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:21:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:21:27

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	08 Oct 2020 16:00:46
User entered 'Day 32'	System	08 Oct 2020 16:00:46

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-11T10:25:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f51cf925-bb79-4177-83e3-be429159b2b1'	System	11 Oct 2020 14:25:43
User entered 'Some interference with activity (2)'	System	11 Oct 2020 14:25:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-11T10:25:39', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f51cf925-bb79-4177-83e3-be429159b2b1' User entered '11 Oct 2020 10:25'	System	11 Oct 2020 14:25:43
	System	11 Oct 2020 14:25:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:00:46

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:00:46

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(33)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	11 Oct 2020 14:24:28
User entered 'Day 33'	System	11 Oct 2020 14:24:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(33)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(33)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(33)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Oct 2020 12:00'	System	11 Oct 2020 14:24:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(33)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Oct 2020 11:59'	System	11 Oct 2020 14:24:28

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(34)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	11 Oct 2020 14:25:43
User entered 'Day 34'	System	11 Oct 2020 14:25:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(34)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(34)

Generated On: 09 Jun 2021 16:06:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(34)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 14:25:43

US3222077

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(34)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 14:25:43

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	14 Sep 2020 23:37:00
User entered 'Day 8'	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:50:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e65c0ded-03da-47a5-bcf4-98d122c74ba5'	System	16 Sep 2020 22:50:37
User entered 'Some interference with activity (2)'	System	16 Sep 2020 22:50:37

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:50:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e65c0ded-03da-47a5-bcf4-98d122c74ba5' User entered '16 Sep 2020 18:50'	System	16 Sep 2020 22:50:37
	System	16 Sep 2020 22:50:37

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 23:37:00

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 00:30:14
User entered 'Day 9'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-17T19:30:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2b4ba5b5-cc31-4c6d-9780-9f827a00b74c'	System	17 Sep 2020 23:31:00
User entered 'No interference with activity (1)'	System	17 Sep 2020 23:31:00

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-17T19:30:55', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2b4ba5b5-cc31-4c6d-9780-9f827a00b74c' User entered '17 Sep 2020 19:30'	System	17 Sep 2020 23:31:00
	System	17 Sep 2020 23:31:00

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 22:50:37
User entered 'Day 10'	System	16 Sep 2020 22:50:37

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-18T20:20:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cdb192d8-b284-4f54-b134-04ef0a724208' User entered 'None (0)'	System	19 Sep 2020 00:20:39
	System	19 Sep 2020 00:20:39

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-18T20:20:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cdb192d8-b284-4f54-b134-04ef0a724208' User entered '18 Sep 2020 20:20'	System	19 Sep 2020 00:20:39
	System	19 Sep 2020 00:20:39

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:50:37

US3222077

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:50:37

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 00:30:14
User entered 'Day 8'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:50:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '51ece671-a674-41fd-a198-99fa408bd96c'	System	16 Sep 2020 22:50:57
User entered 'Prevents daily activity, requires outpatient IV hydration (3)'	System	16 Sep 2020 22:50:57

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:50:53', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '51ece671-a674-41fd-a198-99fa408bd96c' User entered '16 Sep 2020 18:50'	System	16 Sep 2020 22:50:57
	System	16 Sep 2020 22:50:57

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 00:30:14
User entered 'Day 9'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-17T19:31:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f7a4f32e-522f-45eb-b01e-9109a933aa5b'	System	17 Sep 2020 23:31:35
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Sep 2020 23:31:35

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-17T19:31:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f7a4f32e-522f-45eb-b01e-9109a933aa5b' User entered '17 Sep 2020 19:31'	System	17 Sep 2020 23:31:35
	System	17 Sep 2020 23:31:35

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 22:50:57
User entered 'Day 10'	System	16 Sep 2020 22:50:57

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-18T20:20:43', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '012de512-3e62-447a-9147-4557e8a6bf2c'	System	19 Sep 2020 00:20:53
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	19 Sep 2020 00:20:53

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-18T20:20:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '012de512-3e62-447a-9147-4557e8a6bf2c' User entered '18 Sep 2020 20:20'	System	19 Sep 2020 00:20:53
	System	19 Sep 2020 00:20:53

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:50:57

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:50:57

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	17 Sep 2020 23:31:35
User entered 'Day 11'	System	17 Sep 2020 23:31:35

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T06:28:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '19eed321-5e32-40d6-a39f-f6b46bf5ec04'	System	20 Sep 2020 10:28:28
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	20 Sep 2020 10:28:28

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T06:28:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '19eed321-5e32-40d6-a39f-f6b46bf5ec04' User entered '20 Sep 2020 06:28'	System	20 Sep 2020 10:28:28
	System	20 Sep 2020 10:28:28

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 23:31:35

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 23:31:35

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	19 Sep 2020 00:20:53
User entered 'Day 12'	System	19 Sep 2020 00:20:53

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T12:07:10', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4f8f2a11-00ed-4bbf-b436-9708ff57cfca'	System	20 Sep 2020 16:07:18
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Sep 2020 16:07:18

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T12:07:16', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4f8f2a11-00ed-4bbf-b436-9708ff57cfca' User entered '20 Sep 2020 12:07'	System	20 Sep 2020 16:07:18
	System	20 Sep 2020 16:07:18

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:20:53

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:20:53

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	20 Sep 2020 10:28:28
User entered 'Day 13'	System	20 Sep 2020 10:28:28

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-21T21:39:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8c6092dd-b2a4-4001-9f94-d1401391222c'	System	22 Sep 2020 01:40:04
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Sep 2020 01:40:04

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-21T21:39:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8c6092dd-b2a4-4001-9f94-d1401391222c' User entered '21 Sep 2020 21:39'	System	22 Sep 2020 01:40:04
	System	22 Sep 2020 01:40:04

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 10:28:28

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 10:28:28

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	20 Sep 2020 16:07:18
User entered 'Day 14'	System	20 Sep 2020 16:07:18

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-22T12:11:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ae484172-c10b-4850-a63f-99143152c344'	System	22 Sep 2020 16:11:41
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Sep 2020 16:11:41

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-22T12:11:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ae484172-c10b-4850-a63f-99143152c344'	System	22 Sep 2020 16:11:41
User entered '22 Sep 2020 12:11'	System	22 Sep 2020 16:11:41

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 16:07:18

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 16:07:18

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	22 Sep 2020 01:40:04
User entered 'Day 15'	System	22 Sep 2020 01:40:04

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-23T12:01:23', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc5e744b-5201-4164-b750-16b3ac3b164b'	System	23 Sep 2020 16:02:12
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Sep 2020 16:02:12

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-23T12:01:26', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fc5e744b-5201-4164-b750-16b3ac3b164b' User entered '23 Sep 2020 12:01'	System	23 Sep 2020 16:02:12
	System	23 Sep 2020 16:02:12

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 01:40:04

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 01:40:04

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	22 Sep 2020 16:11:41
User entered 'Day 16'	System	22 Sep 2020 16:11:41

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-24T18:53:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '198159e4-61d0-45d8-a52c-09eeff9207ad'	System	24 Sep 2020 22:54:00
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	24 Sep 2020 22:54:00

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-24T18:53:58', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '198159e4-61d0-45d8-a52c-09eeff9207ad' User entered '24 Sep 2020 18:53'	System	24 Sep 2020 22:54:00
	System	24 Sep 2020 22:54:00

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:11:41

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:11:41

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	23 Sep 2020 16:02:12
User entered 'Day 17'	System	23 Sep 2020 16:02:12

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T09:35:53', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7c81a2ab-cd77-4900-8d67-99d48ee02d83'	System	26 Sep 2020 13:36:01
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Sep 2020 13:36:01

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T09:35:57', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7c81a2ab-cd77-4900-8d67-99d48ee02d83' User entered '26 Sep 2020 09:35'	System	26 Sep 2020 13:36:01
	System	26 Sep 2020 13:36:01

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:02:12

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:02:12

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	24 Sep 2020 22:54:00
User entered 'Day 18'	System	24 Sep 2020 22:54:00

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T12:00:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ec07c0d-6849-4c5c-90c5-e9b782552d94' User entered 'None (0)'	System	26 Sep 2020 16:00:47
	System	26 Sep 2020 16:00:47

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T12:00:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4ec07c0d-6849-4c5c-90c5-e9b782552d94' User entered '26 Sep 2020 12:00'	System	26 Sep 2020 16:00:47
	System	26 Sep 2020 16:00:47

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 22:54:00

US3222077

Folder: Diary Dose 2 (1)

Form: Nausea_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 22:54:00

US3222077

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 00:30:14
User entered 'Day 8'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:06:55

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:51:01', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f8d2454c-e17e-4e40-9f2d-301253a6f866'	System	16 Sep 2020 22:51:08
User entered 'None (0)'	System	16 Sep 2020 22:51:08

US3222077

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 00:30:14

US3222077

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:51:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f8d2454c-e17e-4e40-9f2d-301253a6f866'	System	16 Sep 2020 22:51:08
User entered '16 Sep 2020 18:51'	System	16 Sep 2020 22:51:08

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	14 Sep 2020 23:35:45
User entered 'Day 8'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:51:21', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1790ab5c-c022-4486-a9db-556ba29a0ef2'	System	16 Sep 2020 22:51:32
User entered 'Yes (Y)'	System	16 Sep 2020 22:51:32

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-16T18:51:26', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '1790ab5c-c022-4486-a9db-556ba29a0ef2' User entered '16 Sep 2020 18:51'	System	16 Sep 2020 22:51:32
	System	16 Sep 2020 22:51:32

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 23:35:45

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 00:27:19
User entered 'Day 9'	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-17T19:31:09', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fefe38f9-21e0-4c35-b43c-030ed34f1c23'	System	17 Sep 2020 23:31:17
User entered 'Yes (Y)'	System	17 Sep 2020 23:31:17

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-17T19:31:13', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'fefe38f9-21e0-4c35-b43c-030ed34f1c23'	System	17 Sep 2020 23:31:17
User entered '17 Sep 2020 19:31'	System	17 Sep 2020 23:31:17

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 00:27:19

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	16 Sep 2020 22:50:17
User entered 'Day 10'	System	16 Sep 2020 22:50:17

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-18T20:20:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5a5d1962-a297-4e1c-a6ca-336ddacf4efa' User entered 'No (N)'	System	19 Sep 2020 00:21:05
	System	19 Sep 2020 00:21:05

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-18T20:21:03', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5a5d1962-a297-4e1c-a6ca-336ddacf4efa' User entered '18 Sep 2020 20:21'	System	19 Sep 2020 00:21:05
	System	19 Sep 2020 00:21:05

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:50:17

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:50:17

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	17 Sep 2020 23:30:40
User entered 'Day 11'	System	17 Sep 2020 23:30:40

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T06:28:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ba1c63e9-c325-4925-bce7-e56f80f24392'	System	20 Sep 2020 10:28:36
User entered 'No (N)'	System	20 Sep 2020 10:28:36

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T06:28:33', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'ba1c63e9-c325-4925-bce7-e56f80f24392' User entered '20 Sep 2020 06:28'	System	20 Sep 2020 10:28:36
	System	20 Sep 2020 10:28:36

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 23:30:40

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 23:30:40

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	19 Sep 2020 00:20:21
User entered 'Day 12'	System	19 Sep 2020 00:20:21

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T12:07:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2850ff94-7f8f-4300-9203-e41482a8fd1e' User entered 'No (N)'	System	20 Sep 2020 16:07:35
	System	20 Sep 2020 16:07:35

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-20T12:07:33', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2850ff94-7f8f-4300-9203-e41482a8fd1e' User entered '20 Sep 2020 12:07'	System	20 Sep 2020 16:07:35
	System	20 Sep 2020 16:07:35

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:20:21

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:20:21

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	20 Sep 2020 10:28:13
User entered 'Day 13'	System	20 Sep 2020 10:28:13

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-21T21:40:15', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '05547f3b-b909-4086-9284-3b8418a0561e' User entered 'No (N)'	System	22 Sep 2020 01:40:20
	System	22 Sep 2020 01:40:20

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-21T21:40:19', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '05547f3b-b909-4086-9284-3b8418a0561e' User entered '21 Sep 2020 21:40'	System	22 Sep 2020 01:40:20
	System	22 Sep 2020 01:40:20

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 10:28:13

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 10:28:13

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	20 Sep 2020 16:07:09
User entered 'Day 14'	System	20 Sep 2020 16:07:09

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-22T12:11:43', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '6a4d177f-d984-4531-a2cb-1968ecb51e9f' User entered 'Yes (Y)'	System	22 Sep 2020 16:11:48
	System	22 Sep 2020 16:11:48

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'CORRECTION: DATE 22-25 MEDICAL ATTENTION WAS FOR KIDNEY STONES SAE' 09/26 FOLLOW UP WITH DOCTOR'.	douglas winter (b) (4)	05 Oct 2020 10:46:46
Comment added 'DATE 22-25 MEDICAL ATTENTION WAS FOR BACK SURGERY SAE'.	(b) (4)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-22T12:11:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File	douglas winter (b) (4)	05 Oct 2020 10:37:21
OID: '6a4d177f-d984-4531-a2cb-1968ecb51e9f'	(b) (4)	
User entered '22 Sep 2020 12:11'	System	22 Sep 2020 16:11:48
	System	22 Sep 2020 16:11:48

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '22 Sep 2020 12:00'	System	20 Sep 2020 16:07:09

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '23 Sep 2020 11:59'	System	20 Sep 2020 16:07:09

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	22 Sep 2020 01:39:49
User entered 'Day 15'	System	22 Sep 2020 01:39:49

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-23T12:01:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4c69d875-48ee-4810-9f60-51884627f840' User entered 'Yes (Y)'	System	23 Sep 2020 16:02:31
	System	23 Sep 2020 16:02:31

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'CORRECTION: DATE 22-25 MEDICAL ATTENTION WAS FOR KIDNEY STONES SAE' 09/26 FOLLOW UP WITH DOCTOR'.	douglas winter (b) (4) (b) (4)	05 Oct 2020 10:47:00
Comment added "DATE 22-25 MEDICAL ATTENTION WAS FOR BACK SURGERY SAE".	douglas winter (b) (4) (b) (4)	05 Oct 2020 10:39:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-23T12:01:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '4c69d875-48ee-4810-9f60-51884627f840'	System	23 Sep 2020 16:02:31
User entered '23 Sep 2020 12:01'	System	23 Sep 2020 16:02:31

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 01:39:49

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 01:39:49

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	22 Sep 2020 16:11:30
User entered 'Day 16'	System	22 Sep 2020 16:11:30

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-24T18:54:11', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '780c9ca6-fadf-45bb-992c-17dd2613da69'	System	24 Sep 2020 22:54:19
User entered 'Yes (Y)'	System	24 Sep 2020 22:54:19

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'CORRECTION: DATE 22-25 MEDICAL ATTENTION WAS FOR KIDNEY STONES SAE' 09/26 FOLLOW UP WITH DOCTOR'.	douglas winter (b) (4) (b) (4)	05 Oct 2020 10:47:16
Comment added "DATE 22-25 MEDICAL ATTENTION WAS FOR BACK SURGERY SAE".	douglas winter (b) (4) (b) (4)	05 Oct 2020 10:39:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-24T18:54:14', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '780c9ca6-fadf-45bb-992c-17dd2613da69'	System	24 Sep 2020 22:54:19
User entered '24 Sep 2020 18:54'	System	24 Sep 2020 22:54:19

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 16:11:30

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 16:11:30

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	23 Sep 2020 16:01:53
User entered 'Day 17'	System	23 Sep 2020 16:01:53

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T09:36:02', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a5bea503-09c3-4942-9914-a98fd21a1c2a'	System	26 Sep 2020 13:36:09
User entered 'Yes (Y)'	System	26 Sep 2020 13:36:09

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Comment added 'CORRECTION: DATE 22-25 MEDICAL ATTENTION WAS FOR KIDNEY STONES SAE' 09/26 FOLLOW UP WITH DOCTOR'.	douglas winter (b) (4) (b) (4)	05 Oct 2020 10:46:29
Comment added "DATE 22-25 MEDICAL ATTENTION WAS FOR BACK SURGERY SAE' 09/26 FOLLOW UP WITH DOCTOR'.	douglas winter (b) (4) (b) (4)	05 Oct 2020 10:40:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T09:36:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a5bea503-09c3-4942-9914-a98fd21a1c2a'	System	26 Sep 2020 13:36:09
User entered '26 Sep 2020 09:36'	System	26 Sep 2020 13:36:09

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:01:53

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:01:53

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	24 Sep 2020 22:53:37
User entered 'Day 18'	System	24 Sep 2020 22:53:37

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T12:00:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '51cf762c-6d12-4dd9-a5c2-b03e097a0d26' User entered 'No (N)'	System	26 Sep 2020 16:00:56
	System	26 Sep 2020 16:00:56

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-26T12:00:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '51cf762c-6d12-4dd9-a5c2-b03e097a0d26' User entered '26 Sep 2020 12:00'	System	26 Sep 2020 16:00:56
	System	26 Sep 2020 16:00:56

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 22:53:37

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 22:53:37

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	26 Sep 2020 16:00:29
User entered 'Day 20'	System	26 Sep 2020 16:00:29

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-28T12:00:31', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bd25ccdc-9016-4737-8cda-77d957b690e2'	System	28 Sep 2020 16:01:10
User entered 'Yes (Y)'	System	28 Sep 2020 16:01:10

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-28T12:00:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bd25ccdc-9016-4737-8cda-77d957b690e2' User entered '28 Sep 2020 12:00'	System	28 Sep 2020 16:01:10
	System	28 Sep 2020 16:01:10

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 16:00:29

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 16:00:29

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	28 Sep 2020 16:00:34
User entered 'Day 21'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-29T12:21:36', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'c05f624f-c761-4f1a-ac41-0df6b6c16aa1'	System	29 Sep 2020 16:21:50
User entered 'Yes (Y)'	System	29 Sep 2020 16:21:50

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-29T12:21:40', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'c05f624f-c761-4f1a-ac41-0df6c16aa1'	System	29 Sep 2020 16:21:50
User entered '29 Sep 2020 12:21'	System	29 Sep 2020 16:21:50

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	28 Sep 2020 16:00:34
User entered 'Day 22'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-30T22:42:55', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'acd3b018-8844-4c2f-8b6e-2d944cda2b97'	System	01 Oct 2020 02:43:01
User entered 'Yes (Y)'	System	01 Oct 2020 02:43:01

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-09-30T22:42:59', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'acd3b018-8844-4c2f-8b6e-2d944cda2b97' User entered '30 Sep 2020 22:42'	System	01 Oct 2020 02:43:01
	System	01 Oct 2020 02:43:01

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 16:00:34

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	29 Sep 2020 16:21:43
User entered 'Day 23'	System	29 Sep 2020 16:21:43

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-01T12:01:57', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '6ca697f4-39d4-482c-ac58-004c8853f47f' User entered 'Yes (Y)'	System	01 Oct 2020 16:02:46
	System	01 Oct 2020 16:02:46

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-01T12:02:39', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '6ca697f4-39d4-482c-ac58-004c8853f47f' User entered '01 Oct 2020 12:02'	System	01 Oct 2020 16:02:46
	System	01 Oct 2020 16:02:46

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:21:43

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:21:43

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	01 Oct 2020 02:42:51
User entered 'Day 24'	System	01 Oct 2020 02:42:51

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-02T12:01:51', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '0e88f9b5-f251-41c9-93e6-f22f24adfc6f' User entered 'No (N)'	System	02 Oct 2020 16:02:24
	System	02 Oct 2020 16:02:24

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-02T12:01:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '0e88f9b5-f251-41c9-93e6-f22f24adfc6f' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 16:02:24
	System	02 Oct 2020 16:02:24

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 02:42:51

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 02:42:51

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	01 Oct 2020 16:02:11
User entered 'Day 25'	System	01 Oct 2020 16:02:11

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-03T12:00:27', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '217a3662-024d-4bb8-bdf8-86dbbb6e235b' User entered 'No (N)'	System	03 Oct 2020 16:00:41
	System	03 Oct 2020 16:00:41

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-03T12:00:31', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '217a3662-024d-4bb8-bdf8-86dbbb6e235b' User entered '03 Oct 2020 12:00'	System	03 Oct 2020 16:00:41
	System	03 Oct 2020 16:00:41

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:02:11

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:02:11

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	02 Oct 2020 16:02:15
User entered 'Day 26'	System	02 Oct 2020 16:02:15

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-04T12:00:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '53015170-5846-41a6-ac62-5c1959a99208' User entered 'No (N)'	System	04 Oct 2020 16:00:37
	System	04 Oct 2020 16:00:37

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-04T12:00:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '53015170-5846-41a6-ac62-5c1959a99208' User entered '04 Oct 2020 12:00'	System	04 Oct 2020 16:00:37
	System	04 Oct 2020 16:00:37

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 16:02:15

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 16:02:15

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	03 Oct 2020 16:00:27
User entered 'Day 27'	System	03 Oct 2020 16:00:27

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-05T22:38:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b2e05829-be42-4054-832e-4887dec0c020' User entered 'No (N)'	System	06 Oct 2020 02:38:37
	System	06 Oct 2020 02:38:37

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-05T22:38:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'b2e05829-be42-4054-832e-4887dec0c020' User entered '05 Oct 2020 22:38'	System	06 Oct 2020 02:38:37
	System	06 Oct 2020 02:38:37

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '05 Oct 2020 12:00'	System	03 Oct 2020 16:00:27

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '06 Oct 2020 11:59'	System	03 Oct 2020 16:00:27

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	04 Oct 2020 16:00:24
User entered 'Day 28'	System	04 Oct 2020 16:00:24

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-06T12:05:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3f82cb71-d051-470b-a248-11054cce0d62'	System	06 Oct 2020 16:06:01
User entered 'No (N)'	System	06 Oct 2020 16:06:01

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-06T12:05:57', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '3f82cb71-d051-470b-a248-11054cce0d62' User entered '06 Oct 2020 12:05'	System	06 Oct 2020 16:06:01
	System	06 Oct 2020 16:06:01

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 16:00:24

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 16:00:24

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	06 Oct 2020 02:38:28
User entered 'Day 29'	System	06 Oct 2020 02:38:28

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-07T17:21:34', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '158f9c11-54ab-49ba-b790-2f446b243b80' User entered 'Yes (Y)'	System	07 Oct 2020 21:21:48
	System	07 Oct 2020 21:21:48

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-07T17:21:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '158f9c11-54ab-49ba-b790-2f446b243b80' User entered '07 Oct 2020 17:21'	System	07 Oct 2020 21:21:48
	System	07 Oct 2020 21:21:48

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 02:38:28

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 02:38:28

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	06 Oct 2020 16:05:52
User entered 'Day 30'	System	06 Oct 2020 16:05:52

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-08T12:00:37', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '542b6e97-b79c-42b6-9498-81a276725ba1' User entered 'Yes (Y)'	System	08 Oct 2020 16:00:56
	System	08 Oct 2020 16:00:56

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-08T12:00:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '542b6e97-b79c-42b6-9498-81a276725ba1' User entered '08 Oct 2020 12:00'	System	08 Oct 2020 16:00:56
	System	08 Oct 2020 16:00:56

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 16:05:52

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 16:05:52

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	07 Oct 2020 21:21:27
User entered 'Day 31'	System	07 Oct 2020 21:21:27

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-09T14:25:36', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f9e5be10-36dc-4f72-ae6d-7db4fe58ebdd' User entered 'No (N)'	System	11 Oct 2020 14:24:27
	System	11 Oct 2020 14:24:27

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-09T14:25:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'f9e5be10-36dc-4f72-ae6d-7db4fe58ebdd' User entered '09 Oct 2020 14:25'	System	11 Oct 2020 14:24:27
	System	11 Oct 2020 14:24:27

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:21:27

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:21:27

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	08 Oct 2020 16:00:46
User entered 'Day 32'	System	08 Oct 2020 16:00:46

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-11T10:25:44', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8e1ab4c6-14bf-4750-aea9-28ca05f8cccc' User entered 'No (N)'	System	11 Oct 2020 14:25:49
	System	11 Oct 2020 14:25:49

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-11T10:25:47', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8e1ab4c6-14bf-4750-aea9-28ca05f8cccc' User entered '11 Oct 2020 10:25'	System	11 Oct 2020 14:25:49
	System	11 Oct 2020 14:25:49

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 16:00:46

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 16:00:46

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	11 Oct 2020 14:24:28
User entered 'Day 33'	System	11 Oct 2020 14:24:28

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '11 Oct 2020 12:00'	System	11 Oct 2020 14:24:28

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Oct 2020 11:59'	System	11 Oct 2020 14:24:28

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	11 Oct 2020 14:25:43
User entered 'Day 34'	System	11 Oct 2020 14:25:43

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:06:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:06:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:06:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 14:25:43

US3222077

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 16:06:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 14:25:43

US3222077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:15:42

US3222077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '19 Sep 2020'	Albert Garcia (b) (4)	07 Oct 2020 18:15:42

US3222077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	07 Oct 2020 18:15:42

US3222077

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:15:42

US3222077

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:15:45

US3222077

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	07 Oct 2020 18:15:45

US3222077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:16:23

US3222077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '24 Sep 2020'	Albert Garcia (b) (4)	07 Oct 2020 18:16:23

US3222077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	07 Oct 2020 18:16:23

US3222077

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 18:16:23

US3222077

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:16:32

US3222077

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	07 Oct 2020 18:16:32

US3222077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:17:01

US3222077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '3 Oct 2020'	Albert Garcia (b) (4)	07 Oct 2020 18:17:01

US3222077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	07 Oct 2020 18:17:01

US3222077

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:01

US3222077

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:17:05

US3222077

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	07 Oct 2020 18:17:05

US3222077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:17:22

US3222077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '7 Oct 2020'	Albert Garcia (b) (4)	07 Oct 2020 18:17:22

US3222077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	07 Oct 2020 18:17:22

US3222077

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'VISIT3'	System	07 Oct 2020 18:17:22

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered empty.	System	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered empty.	System	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered empty.	System	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered empty.	System	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered empty.	System	07 Oct 2020 18:17:42

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16

US3222077

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16

US3222077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'No (N)'	Albert Garcia (b) (4)	07 Oct 2020 18:17:46

US3222077

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 18:17:46

US3222077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:18:00

US3222077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '7 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 18:18:00

US3222077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '07:48'	Albert Garcia (b) (4)	07 Oct 2020 18:18:00

US3222077

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '7 Oct 2020 07:48'	System	07 Oct 2020 18:18:00

US3222077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 18:18:35

US3222077

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered 'I'	System	07 Oct 2020 18:18:35

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 64'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-11T10:24:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'faee4345-b5a8-4933-b5ac-f5d3d67c5bdd' User entered 'No (N)'	System	11 Oct 2020 14:25:22
	System	11 Oct 2020 14:25:22

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-11T10:24:48', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'faee4345-b5a8-4933-b5ac-f5d3d67c5bdd' User entered 'No (N)'	System	11 Oct 2020 14:25:22
	System	11 Oct 2020 14:25:22

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-11T10:25:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'faee4345-b5a8-4933-b5ac-f5d3d67c5bdd' User entered '11 Oct 2020 10:25:20'	System	11 Oct 2020 14:25:22
	System	11 Oct 2020 14:25:22

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 71'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:59:00
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'SUBJECT ENTERED THIS INERROE. PLEASE SEE EMAIL IN SUBJECT CHART FOR EXPLANATION. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:09:48
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:51:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-17T12:33:39', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7dc6f986-85a8-4ab6-927a-cc5d6c1844d7'	System	17 Oct 2020 16:35:56
User entered 'Yes (Y)'	System	17 Oct 2020 16:35:56

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-17T12:33:51', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7dc6f986-85a8-4ab6-927a-cc5d6c1844d7'	System	17 Oct 2020 16:35:56
User entered 'No (N)'	System	17 Oct 2020 16:35:56

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-17T12:33:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7dc6f986-85a8-4ab6-927a-cc5d6c1844d7'	System	17 Oct 2020 16:35:56
User entered 'No (N)'	System	17 Oct 2020 16:35:56

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-17T12:34:53', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7dc6f986-85a8-4ab6-927a-cc5d6c1844d7'	System	17 Oct 2020 16:35:56
User entered 'Yes (Y)'	System	17 Oct 2020 16:35:56

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-17T12:34:55', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7dc6f986-85a8-4ab6-927a-cc5d6c1844d7'	System	17 Oct 2020 16:35:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Oct 2020 16:35:56

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-17T12:35:42', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '7dc6f986-85a8-4ab6-927a-cc5d6c1844d7' User entered '17 Oct 2020 12:35:42'	System	17 Oct 2020 16:35:56
	System	17 Oct 2020 16:35:56

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 78'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-26T01:43:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '61ecb27c-4a5f-4968-982a-247ec4a81ce3' User entered 'No (N)'	System	26 Oct 2020 05:43:52
	System	26 Oct 2020 05:43:52

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-26T01:43:45', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '61ecb27c-4a5f-4968-982a-247ec4a81ce3'	System	26 Oct 2020 05:43:52
User entered 'No (N)'	System	26 Oct 2020 05:43:52

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-10-26T01:43:50', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '61ecb27c-4a5f-4968-982a-247ec4a81ce3' User entered '26 Oct 2020 01:43:50'	System	26 Oct 2020 05:43:52
	System	26 Oct 2020 05:43:52

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 92'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-09T07:00:08', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd7a09273-966c-4f6f-97ff-0db2002db058'	System	09 Nov 2020 12:00:27
User entered 'No (N)'	System	09 Nov 2020 12:00:27

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-09T07:00:19', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd7a09273-966c-4f6f-97ff-0db2002db058'	System	09 Nov 2020 12:00:27
User entered 'No (N)'	System	09 Nov 2020 12:00:27

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-09T07:00:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'd7a09273-966c-4f6f-97ff-0db2002db058' User entered '09 Nov 2020 07:00:25'	System	09 Nov 2020 12:00:27
	System	09 Nov 2020 12:00:27

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered 'Day 99'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-15T19:20:55', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cfe61997-21f8-4c01-9b6d-91b7e97d0d18' User entered 'No (N)'	System	16 Nov 2020 00:21:13
	System	16 Nov 2020 00:21:13

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-15T19:21:05', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cfe61997-21f8-4c01-9b6d-91b7e97d0d18'	System	16 Nov 2020 00:21:13
User entered 'No (N)'	System	16 Nov 2020 00:21:13

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-15T19:21:10', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'cfe61997-21f8-4c01-9b6d-91b7e97d0d18' User entered '15 Nov 2020 19:21:10'	System	16 Nov 2020 00:21:13
	System	16 Nov 2020 00:21:13

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 22:42:55

US3222077

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:03:32
Data entry locked.	System	10 Aug 2020 22:42:55
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 22:42:55

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-21T21:53:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'dbc5b306-073c-4a74-86d5-1733b0f8d510' User entered 'No (N)'	System	22 Nov 2020 02:53:41
	System	22 Nov 2020 02:53:41

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-21T21:53:33', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'dbc5b306-073c-4a74-86d5-1733b0f8d510'	System	22 Nov 2020 02:53:41
User entered 'No (N)'	System	22 Nov 2020 02:53:41

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-21T21:53:38', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'dbc5b306-073c-4a74-86d5-1733b0f8d510'	System	22 Nov 2020 02:53:41
User entered '21 Nov 2020 21:53:38'	System	22 Nov 2020 02:53:41

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-26T09:28:47', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8545fdcb-8b87-40ae-b85a-d253610dc201' User entered 'No (N)'	System	26 Nov 2020 14:29:04
	System	26 Nov 2020 14:29:04

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-26T09:28:53', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8545fdcb-8b87-40ae-b85a-d253610dc201' User entered 'No (N)'	System	26 Nov 2020 14:29:04
	System	26 Nov 2020 14:29:04

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-11-26T09:28:57', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8545fdcb-8b87-40ae-b85a-d253610dc201' User entered '26 Nov 2020 09:28:57'	System	26 Nov 2020 14:29:04

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-05T17:59:22', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '542d4b3c-ee5b-4082-9f2b-3f3450a7b6ca' User entered 'No (N)'	System	05 Dec 2020 22:59:35
	System	05 Dec 2020 22:59:35

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-05T17:59:27', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '542d4b3c-ee5b-4082-9f2b-3f3450a7b6ca' User entered 'No (N)'	System	05 Dec 2020 22:59:35
	System	05 Dec 2020 22:59:35

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-05T17:59:31', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '542d4b3c-ee5b-4082-9f2b-3f3450a7b6ca' User entered '05 Dec 2020 17:59:31'	System	05 Dec 2020 22:59:35
	System	05 Dec 2020 22:59:35

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-09T00:05:18', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a7b8a5a9-4f80-4d02-92d5-3753c9de35c1' User entered 'No (N)'	System	09 Dec 2020 05:05:41
	System	09 Dec 2020 05:05:41

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-09T00:05:31', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a7b8a5a9-4f80-4d02-92d5-3753c9de35c1' User entered 'No (N)'	System	09 Dec 2020 05:05:41
	System	09 Dec 2020 05:05:41

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-09T00:05:39', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'a7b8a5a9-4f80-4d02-92d5-3753c9de35c1' User entered '09 Dec 2020 00:05:39'	System	09 Dec 2020 05:05:41
	System	09 Dec 2020 05:05:41

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-18T12:58:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8f417330-f336-49d7-86e5-2b6748faec30'	System	18 Dec 2020 17:59:00
User entered 'No (N)'	System	18 Dec 2020 17:59:00

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-18T12:58:52', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8f417330-f336-49d7-86e5-2b6748faec30'	System	18 Dec 2020 17:59:00
User entered 'No (N)'	System	18 Dec 2020 17:59:00

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-18T12:58:56', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '8f417330-f336-49d7-86e5-2b6748faec30' User entered '18 Dec 2020 12:58:56'	System	18 Dec 2020 17:59:00
	System	18 Dec 2020 17:59:00

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-25T13:35:20', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e20b199b-79d4-4291-b2e3-cd501015e7a8'	System	25 Dec 2020 18:35:33
User entered 'No (N)'	System	25 Dec 2020 18:35:33

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-25T13:35:25', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e20b199b-79d4-4291-b2e3-cd501015e7a8'	System	25 Dec 2020 18:35:33
User entered 'No (N)'	System	25 Dec 2020 18:35:33

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-25T13:35:29', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'e20b199b-79d4-4291-b2e3-cd501015e7a8'	System	25 Dec 2020 18:35:33
User entered '25 Dec 2020 13:35:29'	System	25 Dec 2020 18:35:33

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-30T12:33:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2cd4ffce-1077-4728-8aa7-61556f20bd0a' User entered 'No (N)'	System	30 Dec 2020 17:34:01
	System	30 Dec 2020 17:34:01

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-30T12:33:54', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2cd4ffce-1077-4728-8aa7-61556f20bd0a' User entered 'No (N)'	System	30 Dec 2020 17:34:01
	System	30 Dec 2020 17:34:01

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2020-12-30T12:33:58', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '2cd4ffce-1077-4728-8aa7-61556f20bd0a' User entered '30 Dec 2020 12:33:58'	System	30 Dec 2020 17:34:01
	System	30 Dec 2020 17:34:01

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-06T11:20:30', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5afeffd3-f19f-4853-a59f-ed8961861875' User entered 'No (N)'	System	06 Jan 2021 16:20:47

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-06T11:20:32', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5afeffd3-f19f-4853-a59f-ed8961861875'	System	06 Jan 2021 16:20:47
User entered 'No (N)'	System	06 Jan 2021 16:20:47

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-06T11:20:35', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '5afeffd3-f19f-4853-a59f-ed8961861875' User entered '06 Jan 2021 11:20:35'	System	06 Jan 2021 16:20:47

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-13T18:25:43', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '20122464-f5b3-4115-acf3-fd4241301cea' User entered 'No (N)'	System	13 Jan 2021 23:25:55
	System	13 Jan 2021 23:25:55

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-13T18:25:46', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '20122464-f5b3-4115-acf3-fd4241301cea' User entered 'No (N)'	System	13 Jan 2021 23:25:55
	System	13 Jan 2021 23:25:55

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-13T18:25:49', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: '20122464-f5b3-4115-acf3-fd4241301cea' User entered '13 Jan 2021 18:25:49'	System	13 Jan 2021 23:25:55
	System	13 Jan 2021 23:25:55

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-20T19:44:14', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bfc45bcf-4598-42a3-b8a4-060d6a3d4601' User entered 'No (N)'	System	21 Jan 2021 00:44:29

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

Have you been exposed to someone with 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 (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-20T19:44:19', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bfc45bcf-4598-42a3-b8a4-060d6a3d4601' User entered 'No (N)'	System	21 Jan 2021 00:44:29

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DCC4AE56-C608-4322-968E-60D76277036E)', Time: '2021-01-20T19:44:24', User OID: 'PatientReportedOutcome (US3222077)', ODM File OID: 'bfc45bcf-4598-42a3-b8a4-060d6a3d4601' User entered '20 Jan 2021 19:44:24'	System	21 Jan 2021 00:44:29
	System	21 Jan 2021 00:44:29

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:20:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:20:22

US3222077

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:06:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:20:22
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:20:22

US3222077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:24:32

US3222077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:24:32

US3222077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:24:32

US3222077

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:24:32

US3222077

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Nov 2020 20:24:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 20:24:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 20:24:43
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:24:38
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 20:24:38

US3222077

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:46:16
User entered '1'	System	18 Nov 2020 20:24:43
User entered empty.	System	18 Nov 2020 20:24:38

US3222077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	heather jackson (b) (4)	10 Dec 2020 19:10:18

US3222077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '07 Dec 2020'	heather jackson (b) (4)	10 Dec 2020 19:10:18

US3222077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	10 Dec 2020 19:10:18

US3222077

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	heather jackson (b) (4)	10 Dec 2020 19:10:18

US3222077

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:09:13

US3222077

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User entered 'I'	System	29 Dec 2020 16:09:13

US3222077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:23:24

US3222077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:23:24

US3222077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:23:24

US3222077

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 13:23:24

US3222077

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:48:37

US3222077

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User entered 'I'	System	11 Feb 2021 14:48:37

US3222077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:49:05

US3222077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:49:05

US3222077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:49:05

US3222077

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:49:05

US3222077

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:47

US3222077

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:31:12
User entered 'I'	System	11 Feb 2021 14:59:47

US3222077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:35:01
User entered 'Yes (Y)'	Vicki Miller (b) (4)	24 Feb 2021 23:39:43
	(b) (4)	
	(b) (4), (b) (6)	

US3222077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:35:01
User entered '24 Feb 2021'	Vicki Miller (b) (4)	24 Feb 2021 23:39:43
	(b) (4)	
	(b) (4), (b) (6)	

US3222077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:35:01
User entered 'Clinic (Clinic)'	Vicki Miller (b) (4)	24 Feb 2021 23:39:43
	(b) (4)	
	(b) (4), (b) (6)	

US3222077

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User entered 'VISIT4'	System	24 Feb 2021 23:39:43

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User entered empty.	System	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User entered empty.	System	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User entered empty.	System	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User entered empty.	System	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User entered empty.	System	31 Mar 2021 12:26:38

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07

US3222077

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:06:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07

US3222077

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:35:01
User entered 'No (N)'	Vicki Miller (b) (4)	24 Feb 2021 23:39:49
	(b) (4)	
	(b) (4), (b) (6)	

US3222077

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:06:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:35:01
User entered empty.	Vicki Miller (b) (4)	24 Feb 2021 23:39:49
	(b) (4)	
	(b) (4), (b) (6)	

US3222077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:15:53

US3222077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:15:53

US3222077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '7:30'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:15:53

US3222077

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User entered '24 Feb 2021 7:30'	System	26 Mar 2021 20:15:53

US3222077

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:35:01
User entered 'Yes (Y)'	Vicki Miller (b) (4)	24 Feb 2021 23:39:53
	(b) (4)	
	(b) (4), (b) (6)	

US3222077

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:30:07
User entered 'I'	System	24 Feb 2021 23:39:53

US3222077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Apr 2021 12:07:50

US3222077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
	(b) (4)	
User entered '07 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 12:07:50

US3222077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:07:50

US3222077

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:06:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:07:50

US3222077

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:07:57

US3222077

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:06:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 12:07:57

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:59:34

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:59:34

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:59:34

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:06:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 19:59:34

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:14:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:41:09

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:14:59
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:41:09

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 01:41:19
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 01:41:19
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:06:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered empty.	System	15 Jan 2021 19:59:52

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:03:26

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:03:26

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '14:00'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:03:26

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:06:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '15 Jan 2021 14:00'	System	15 Jan 2021 20:03:26

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:03:38

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:03:38

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '14:05'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:03:38

US3222077

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:06:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:10:42
User entered '15 Jan 2021 14:05'	System	15 Jan 2021 20:03:38

US3222077

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:06:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:04
User closed query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 2 Record, symptom of Fatigue, Muscle aches all over, and Nausea/Vomiting persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:50:38
Query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 2 Record, symptom of Fatigue, Muscle aches all over, and Nausea/Vomiting persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'AE added for symptoms. Sources added for symptoms' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 20:39:33
User opened query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Please note, Per Diary Dose 2 Record, symptom of Fatigue, Muscle aches all over, and Nausea/Vomiting persist beyond Day 7. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 09:02:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:13:42
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:29:11
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 23:25:31

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 15:15:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered	System	28 Sep 2020 14:11:45
'USA-US104-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	28 Sep 2020 14:11:45

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'PV Query: Please consider merging the 2 events of kidney stones into 1 single event with earliest start and latest stop date (currently the onset and end dates of the 2 events overlap).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:55:17
Query 'PV Query: Please consider merging the 2 events of kidney stones into 1 single event with earliest start and latest stop date (currently the onset and end dates of the 2 events overlap).' answered with 'WE WILL MERGE THE 2 INTO ONE ADN ADD LITHOTRIPSY TO THE CON PROCEUDRES PAGE.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:56:53
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:57
User opened query 'PV Query: Please consider merging the 2 events of kidney stones into 1 single event with earliest start and latest stop date (currently the onset and end dates of the 2 events overlap).' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:49:37
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Sep 2020 16:37:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Sep 2020 16:37:39
Data point term sent to Coder	System	27 Sep 2020 16:37:24
User entered 'Kidney stones'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'PV Query: Please assess if 15 Sep 2020 should be considered the event start date? Please consider updating event start date to when signs and symptoms started.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:55:26
User closed query 'PV Query: Concomitant medication morphine drip with indication of kidney stones was dated 18 Sep 2020. Should the event start date change to 18 Sep 2020 or should the morphine date change to 22 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:55:23
Query 'PV Query: Please assess if 15 Sep 2020 should be considered the event start date? Please consider updating event start date to when signs and symptoms started.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	10 Nov 2020 19:57:36
User entered '15 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 19:57:29
Query 'PV Query: Concomitant medication morphine drip with indication of kidney stones was dated 18 Sep 2020. Should the event start date change to 18 Sep 2020 or should the morphine date change to 22 Sep 2020?' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	10 Nov 2020 19:57:04
DataPoint Un-verified.	Albert Garcia (b) (4)	10 Nov 2020 19:50:13
User entered '18 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 19:50:13
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:57
User opened query 'PV Query: Please assess if 15 Sep 2020 should be considered the event start date? Please consider updating event start date to when signs and symptoms started.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:47:22
User opened query 'PV Query: Concomitant medication morphine drip with indication of kidney stones was dated 18 Sep 2020. Should the event start date change to 18 Sep 2020 or should the morphine date change to 22 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:46:24
User entered '22 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	09 Oct 2020 17:31:43

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	09 Oct 2020 17:27:19
User entered '18 Sep 2020'	douglas winter (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 17:29:20
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:29:20
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 17:27:19
User entered '12:05' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:27:19
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Sep 2020 16:37:39
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:37:39
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Sep 2020 16:36:52
User entered '00:00'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:29:20
User entered '27 Sep 2020 12:05'	System	09 Oct 2020 17:27:19
User entered empty.	System	27 Sep 2020 16:37:39
User entered '18 Sep 2020 00:00'	System	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:21:00
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '2 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:39:31
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. The end date was reported as 25 SEP 2020, however the outcome was recovering/resolving.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:25:41
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	09 Oct 2020 17:32:22
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	09 Oct 2020 17:32:22
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	09 Oct 2020 17:31:43
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. The end date was reported as 25 SEP 2020, however the outcome was recovering/resolving.' answered with 'OCT/02 SUBJECT HAD LITHOTRIPSY AND THEN HE WAS FULLY RECOVERED.' (Site from Safety).	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:30:47
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	09 Oct 2020 17:30:40
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	09 Oct 2020 17:29:20
User entered '25 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:29:20
User entered '02 Oct 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:21:00

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. The end date was reported as 25 SEP 2020, however the outcome was recovering/resolving.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	07 Oct 2020 19:00:28
	douglas winter (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:07:57
User closed query 'PV query: Please confirm the grade/severity for the event. Per the EDC, it was reported as grade 2 and per the SAE form submitted, it was reported as grade 4.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:25:43
Query 'PV query: Please confirm the grade/severity for the event. Per the EDC, it was reported as grade 2 and per the SAE form submitted, it was reported as grade 4.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4)	09 Oct 2020 17:21:17
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change:	douglas winter (b) (4)	09 Oct 2020 17:21:00
Data Entry Error	(b) (4)	
User opened query 'PV query: Please confirm the grade/severity for the event. Per the EDC, it was reported as grade 2 and per the SAE form submitted, it was reported as grade 4.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:03:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	douglas winter (b) (4)	27 Sep 2020 16:36:52
	(b) (4)	

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	27 Sep 2020 16:38:46
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:38:46
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	27 Sep 2020 16:37:39
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		27 Sep 2020 16:37:39
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		27 Sep 2020 16:37:39
User entered '1' reason for change: Data Entry Error douglas winter	(b) (4)	27 Sep 2020 16:37:39
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	27 Sep 2020 16:36:52
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '22 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:27:19
User entered '18 Sep 2020'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:07:57
User closed query 'PV Query: Please confirm event end date of '25 Sep 2020'; as it was reported that the subject was not fully recovered until after lithotripsy which was completed on '02 Oct 2020'.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:04:41
Query 'PV Query: Please confirm event end date of '25 Sep 2020'; as it was reported that the subject was not fully recovered until after lithotripsy which was completed on '02 Oct 2020'.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4)	19 Oct 2020 16:39:42
	(b) (4)	
User entered '23 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:39:31
	(b) (4)	
User opened query 'PV Query: Please confirm event end date of '25 Sep 2020'; as it was reported that the subject was not fully recovered until after lithotripsy which was completed on '02 Oct 2020'.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:16:38
User entered '25 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	09 Oct 2020 17:27:19
	(b) (4)	
User entered '18 Sep 2020'	douglas winter (b) (4)	27 Sep 2020 16:36:52
	(b) (4)	

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:07:57
User closed query 'PV Query: Please consider updating action taken to Not Applicable, as both doses of IP were administered prior to the event onset.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:04:45
Query 'PV Query: Please consider updating action taken to Not Applicable, as both doses of IP were administered prior to the event onset.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4)	19 Oct 2020 16:39:53
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4)	19 Oct 2020 16:39:31
reason for change: Data Entry Error	(b) (4)	
User entered 'Dose Delayed (DOSE DELAYED)'	douglas winter (b) (4)	19 Oct 2020 16:34:49
reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: Please consider updating action taken to Not Applicable, as both doses of IP were administered prior to the event onset.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:17:10
User entered 'None (NONE)'	douglas winter (b) (4)	27 Sep 2020 16:36:52
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per DM CLR: SAE Narrative = Patient was given MORPHINE and OXYTOCIN. However, these medications were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. ' (Site from DM). Query 'Per DM CLR: SAE Narrative = Patient was given MORPHINE and OXYTOCIN. However, these medications were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. ' answered with 'CORRECTED' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 12:31:47
DataPoint Verified.	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:00:54
	(b) (4), (b) (6)	04 Nov 2020 21:07:57
User opened query 'Per DM CLR: SAE Narrative = Patient was given MORPHINE and OXYTOCIN. However, these medications were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. ' (Site from DM). Query 'Per DM CLR: SAE Narrative = Patient was given MORPHINE and OXYTOCIN. However, these medications were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:56:15
User opened query 'Per DM CLR: SAE Narrative = Patient was given MORPHINE and OXYTOCIN. However, these medications were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. ' (Site from DM). User entered 'I'	(b) (4), (b) (6)	01 Nov 2020 01:56:00
	(b) (4), (b) (6)	01 Nov 2020 01:55:53
	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per CDM: Please verify if this field should be ticked as there is a ConProc recorded that match this AE during this timeframe. Please review and update AE page as appropriate or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 21:54:32
Query 'Per CDM: Please verify if this field should be ticked as there is a ConProc recorded that match this AE during this timeframe. Please review and update AE page as appropriate or provide clarification.'	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 15:05:40
answered with 'UPDATED' (Site from DM).		
User entered '1' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Dec 2020 15:05:20
User opened query 'Per CDM: Please verify if this field should be ticked as there is a ConProc recorded that match this AE during this timeframe. Please review and update AE page as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:54:40
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. If verified as correct, ensure that ConProc indication = ADVERSE EVENT. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:54:40
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. If verified as correct, ensure that ConProc indication = ADVERSE EVENT. Review and update eCRF as appropriate.'	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:15:07
answered with 'correct as entered Lithotripsy done outpatient' (Site from DM).		
User entered '0' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:12:20
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	01 Dec 2020 14:52:41
User entered '1' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	01 Dec 2020 14:52:41

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that mach this AE during this timeframe. If verified as correct, ensure that ConProc indication = ADVERSE EVENT. Review and update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 23:54:51
	(b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered '0'	douglas winter (b) (4)	27 Sep 2020 16:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
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)	12 Oct 2020 13:25:49
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 'SUBJECT FULLY RECOVERED AFTER HAVING LITHOTRIPSY ON OCT/02/2020.' (Site from Safety).	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:39:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:32:22
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:30:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Oct 2020 17:21:00
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)	07 Oct 2020 19:02:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:57
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per DM CLR: SAE Narrative = SUBJECT WENT TO THE ER FOR KIDNEY STONES ON 18/SEP/2020. HE SAID IT WAS COMING ON "COULD FEEL IT AND I WANTED TO SEEK TREATMENT BEFORE IT GOT BAD. HE RATED IT A MODERATE GRADE 2. HE WAS GIVEN MORPHINE, AND FLUIDS AND OXYCOTIN AT DISCHARGE SAME DAY. However, the medications recorded were not during this timeframe. Please review and reconcile CM data and AE Narrative as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 11:33:47
User closed query 'Per DM CLR: SAE Narrative = SUBJECT WENT TO THE ER FOR KIDNEY STONES ON 18/SEP/2020. However, Morphine and Oxytocin were given on 15SEP2020. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:32:44
User closed query 'PV Query: Please consider whether UTI met separate AE/SAE reporting criteria.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 17:13:18
User closed query 'PV Query: Please consider merging the 2 events of kidney stones into 1 single event with earliest start and latest stop date (currently the onset and end dates of the 2 events overlap).' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 17:13:07
User closed query 'PV Query: Concomitant medication morphine drip with indication of kidney stones was dated 18 Sep 2020. Should the event start date change to 18 Sep 2020 or should the morphine date change to 22 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 17:12:45
Query 'Per DM CLR: SAE Narrative = SUBJECT WENT TO THE ER FOR KIDNEY STONES ON 18/SEP/2020. However, Morphine and Oxytocin were given on 15SEP2020. Please review and reconcile data as appropriate.' answered with 'con meds addressed' (Site from DM).	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:42:37
Query 'PV Query: Please consider whether UTI met separate AE/SAE reporting criteria.' answered with 'separate' (Site from Safety).	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:42:24

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider merging the 2 events of kidney stones into 1 single event with earliest start and latest stop date (currently the onset and end dates of the 2 events overlap).' answered with 'merged' (Site from Safety).	gail lavine (b) (4)	01 Dec 2020 15:42:18
Query 'PV Query: Concomitant medication morphine drip with indication of kidney stones was dated 18 Sep 2020. Should the event start date change to 18 Sep 2020 or should the morphine date change to 22 Sep 2020?' answered with 'updated con meds' (Site from Safety).	gail lavine (b) (4)	01 Dec 2020 15:41:55
Query 'Per DM CLR: SAE Narrative = SUBJECT WENT TO THE ER FOR KIDNEY STONES ON 18/SEP/2020. HE SAID IT WAS COMING ON "COULD FEEL IT AND I WANTED TO SEEK TREATMENT BEFORE IT GOD BAD. HE RATED IT A MODERATE GRADE 2. HE WAS GIVEN MORPHINE, AND FLUIDS AND OXYCOTIN AT DISCHARGE SAME DAY. However, the medications recorded were not during this timeframe. Please review and reconcile CM data and AE Narrative as appropriate. Otherwise, clarify.' answered with 'adding 2 separate entries' (Site from DM).	gail lavine (b) (4)	01 Dec 2020 15:12:21
User opened query 'Per DM CLR: SAE Narrative = SUBJECT WENT TO THE ER FOR KIDNEY STONES ON 18/SEP/2020. HE SAID IT WAS COMING ON "COULD FEEL IT AND I WANTED TO SEEK TREATMENT BEFORE IT GOD BAD. HE RATED IT A MODERATE GRADE 2. HE WAS GIVEN MORPHINE, AND FLUIDS AND OXYCOTIN AT DISCHARGE SAME DAY. However, the medications recorded were not during this timeframe. Please review and reconcile CM data and AE Narrative as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:54:36
User opened query 'Per DM CLR: SAE Narrative = SUBJECT WENT TO THE ER FOR KIDNEY STONES ON 18/SEP/2020. However, Morphine and Oxytocin were given on 15SEP2020. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:54:29

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider whether UTI met separate AE/SAE reporting criteria. (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:48:12
User opened query 'PV Query: Please consider merging the 2 events of kidney stones into 1 single event with earliest start and latest stop date (currently the onset and end dates of the 2 events overlap).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:47:56
User opened query 'PV Query: Concomitant medication morphine drip with indication of kidney stones was dated 18 Sep 2020. Should the event start date change to 18 Sep 2020 or should the morphine date change to 22 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 14:47:42
User closed query 'Per DM CLR: SAE Narrative = HE WAS DISCHARGED WITHOUT PASSING THE STONE AND IS SCHEDULED FOR LITHOTRIPSY ON 02/OCT/2020. Please confirm if this procedure was done. If yes, please record this to the ConProc eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:34:58
User closed query 'PV Query: Please consider whether UTI met separate AE/SAE reporting criteria. (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:55:32
Query 'PV Query: Please consider whether UTI met separate AE/SAE reporting criteria.' answered with 'WILL CONFER WITH PI TO MAKE THAT DETERMINATION. AT THIS TIME, IT APPEARS TO BE A DIRECT RESULT OF THE ORIGINAL AE/SAE.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:06:59
Query 'Per DM CLR: SAE Narrative = HE WAS DISCHARGED WITHOUT PASSING THE STONE AND IS SCHEDULED FOR LITHOTRIPSY ON 02/OCT/2020. Please confirm if this procedure was done. If yes, please record this to the ConProc eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:05:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:07:57

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = HE WAS DISCHARGED WITHOUT PASSING THE STONE AND IS SCHEDULED FOR LITHOTRIPSY ON 02/OCT/2020. Please confirm if this procedure was done. If yes, please record this to the ConProc eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:57:14
Query 'Per DM CLR: SAE Narrative = SUBJECT WENT TO THE ER FOR KIDNEY STONES ON 18/SEP/2020. Please review and confirm if KIDNEY STONES started on this day. If yes, please update AE start date as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:56:53
User opened query 'Per DM CLR: SAE Narrative = SUBJECT WENT TO THE ER FOR KIDNEY STONES ON 18/SEP/2020. Please review and confirm if KIDNEY STONES started on this day. If yes, please update AE start date as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:56:31
User opened query 'PV Query: Please consider whether UTI met separate AE/SAE reporting criteria. (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:49:57
User closed query 'PV Query: Please add start date for medical history Diabetes Mellitus Type II to eCRF. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:05:12
User closed query 'PV Query: Previous paper SAE form reported concomitant medication Tylenol. Please add to eCRF if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:05:09
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:05:04
User closed query 'PV Query: Previous paper SAE form reported medical history of osteoarthritis. Please add to eCRF if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:04:59
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 14:04:57

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WENT TO THE ER FOR KIDNEY STONES HE SAID IT WAS COMING ON "COULD FEEL IT AND I WANTED TO SEEK TREATMENT BEFORE IT GOD BAD. HE RATED IT A MODERATE GRADE 2. HE WAS GIVEN MORPHINE, AND FLUIDS AND OXYCOTIN AT DISCHARGE SAME DAY. NOT AN SAE, I first found out today 27/Sep/2020 @ 12:05 pm while calling patient about a solicited event. SUBJECT WENT TO THE ER FOR KIDNEY STONES on 18/Sep/2020. HE SAID IT WAS COMING ON "COULD FEEL IT AND I WANTED TO SEEK TREATMENT BEFORE IT GOD BAD. HE RATED IT A MODERATE GRADE 2. HE WAS GIVEN MORPHINE, AND FLUIDS AND OXYCOTIN AT DISCHARGE SAME DAY. I RECORDED THIS EVENT AS AN ADVERSE EVENT. Corrected discharge date with medical records received. Then he went back to the ER on 22/SEP/2020 FOR KIDNEY STONES AND WAS ADMITTED AND DISCHARGED ON 23/SEP/2020. HE WAS DISCHARGED WITHOUT PASSING THE STONE AND IS SCHEDULED FOR LITHOTRIPSY ON 02/Oct/2020.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:02:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'CT OF ABDOMEN 22 September 2020 RIGHT HYDROURETERONEPHROSIS, NONOBSTRUCTIVE LEFT NEPHROLITHIASIS. CT OF PELVIS 22 September 2020 RIGHT HYDROURETERONEPHROSIS, NONOBSTRUCTIVE LEFT NEPHROLITHIASIS. X-RAY OF ABDOMEN 23 September 2020 MID URETERAL STONE ' (Site from Safety).	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:58:38

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'ADDED TREATMENT MEDICATIONS' (Site from Safety).	douglas winter (b) (4)	19 Oct 2020 16:57:49
Query 'PV Query: Please add start date for medical history Diabetes Mellitus Type II to eCRF. If unknown, please state so.' answered with 'ADDED START YEAR' (Site from Safety).	douglas winter (b) (4)	19 Oct 2020 16:48:33
Query 'PV Query: Previous paper SAE form reported concomitant medication Tylenol. Please add to eCRF if applicable.' answered with 'TYLENOL WAS ADDED IN ERROR' (Site from Safety).	douglas winter (b) (4)	19 Oct 2020 16:45:46
Query 'PV Query: Previous paper SAE form reported medical history of osteoarthritis. Please add to eCRF if applicable.' answered with 'TYLENOL WAS ADDED IN ERROR' (Site from Safety).	douglas winter (b) (4)	19 Oct 2020 16:45:26
User opened query 'PV Query: Please add start date for medical history Diabetes Mellitus Type II to eCRF. If unknown, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:17:01
User opened query 'PV Query: Previous paper SAE form reported concomitant medication Tylenol. Please add to eCRF if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:16:54
User opened query 'PV Query: Previous paper SAE form reported medical history of osteoarthritis. Please add to eCRF if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:16:47
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:16:21
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:16:14

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide end date for appendectomy in MH.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:52:41
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:52:39
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:52:34
User closed query 'PV Query: Please provide results of any COVID-19 testing performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 15:52:31
Query 'PV Query: Please provide end date for appendectomy in MH.' answered with 'DISCHARGE ORDERS HAVE BEEN REQUESTED' (Site from Safety).	Albert Garcia (b) (4)	12 Oct 2020 16:59:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'DISCHARGE ORDERS REQUESTED' (Site from Safety).	Albert Garcia (b) (4)	12 Oct 2020 16:59:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'DISCHARGE ORDERS REQUESTED' (Site from Safety).	Albert Garcia (b) (4)	12 Oct 2020 16:59:05
Query 'PV Query: Please provide results of any COVID-19 testing performed during hospitalization.' answered with 'NOT TESTED.' (Site from Safety).	Albert Garcia (b) (4)	12 Oct 2020 16:58:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Per SAE Report, the subject is scheduled for a lithotripsy. Please confirm date of lithotripsy as it is currently dated for 02 SEP 2020 and provide results when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 13:25:54
Query 'PV Query: Per SAE Report, the subject is scheduled for a lithotripsy. Please confirm date of lithotripsy as it is currently dated for 02 SEP 2020 and provide results when available.' answered with '02/OCT/2020' (Site from Safety).	douglas winter (b) (4)	09 Oct 2020 17:40:27
User opened query 'PV Query: Please provide end date for appendectomy in MH.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:02:42
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:02:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:00:40
User opened query 'PV Query: Please provide results of any COVID-19 testing performed during hospitalization.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:00:14
User opened query 'PV Query: Per SAE Report, the subject is scheduled for a lithotripsy. Please confirm date of lithotripsy as it is currently dated for 02 SEP 2020 and provide results when available.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 18:59:45
User entered 'Subject went to the ER for kidney stones He said it was coming on "could feel it and i wanted to seek treatment before it got bad. He rated it a moderate grade 2. He was given morphine, and fluids and Oxycotin at discharge same day. NOT an SAE,'	douglas winter (b) (4)	27 Sep 2020 16:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 16:38:46
User entered '0'	System	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Sep 2020 16:36:52

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 19:41:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 19:41:53
Data point term sent to Coder	System	16 Nov 2020 19:40:54
User entered 'Urinary tract infection'	douglas winter (b) (4)	16 Nov 2020 19:40:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '22 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User entered empty.	System	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '23 Sep 2020'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User entered empty.	System	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) douglas winter (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per CDM: ConMed Check box is updated however corresponding ConMed page is not updated. Please review and update accordingly or explain' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 06:20:59
Query 'Per CDM: ConMed Check box is updated however corresponding ConMed page is not updated. Please review and update accordingly or explain' answered with 'discharge summary only mentions Empiric antibiotic which was entered in con meds' (Site from DM).	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:33:56
User opened query 'Per CDM: ConMed Check box is updated however corresponding ConMed page is not updated. Please review and update accordingly or explain' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:54:43
User entered 'I'	douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'While the subject was in the hospital for their SAE, he was also treated for a UTI.'	(b) (4) douglas winter (b) (4)	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User entered '0'	System	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11
User entered '1'	System	16 Nov 2020 19:40:02

US3222077

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:11

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 20:32:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 20:32:36
Data point term sent to Coder	System	19 Apr 2021 20:31:25
User entered 'fatigue'	(b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:38:15
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Apr 2021 20:32:20
User entered '12:00' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:32:20
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 20:31:12
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User entered '10 Sep 2020 12:00'	System	19 Apr 2021 20:32:20
User entered empty.	System	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '11 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Apr 2021 20:32:20
User entered '12:00' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 20:32:20
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Apr 2021 20:31:12
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User entered '11 Oct 2020 12:00'	System	19 Apr 2021 20:32:20
User entered empty.	System	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User entered '0'	System	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06
User entered '1'	System	19 Apr 2021 20:38:15
User entered '0'	System	19 Apr 2021 20:31:12

US3222077

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:06

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User closed query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:23:17
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 14:33:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 14:33:19
Data point term sent to Coder	System	23 Apr 2021 13:07:46
Query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' answered with 'added location' (Site from DM).	Crystal Paccione (b) (4)	23 Apr 2021 13:07:06
Coding entries removed.	Crystal Paccione (b) (4)	23 Apr 2021 13:06:56
User entered 'MUSCLE ACHES (myalgia whole body)' reason for change: Data Entry Error	Crystal Paccione (b) (4)	23 Apr 2021 13:06:56
User opened query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 17:48:30
Query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 09:22:29
User opened query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 08:50:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 20:34:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 20:34:35
Data point term sent to Coder	System	19 Apr 2021 20:33:29
User entered 'muscle aches'	(b) (4), (b) (6)	19 Apr 2021 20:33:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 20:38:24
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 20:33:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User entered empty.	System	19 Apr 2021 20:33:07

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User entered empty.	System	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User entered '0'	System	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51
User entered '1'	System	19 Apr 2021 20:38:24
User entered '0'	System	19 Apr 2021 20:33:07

US3222077

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:51

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 12:38:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 12:38:08
Data point term sent to Coder	System	19 Apr 2021 20:34:33
User entered 'nausea/ vomiting'	(b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Apr 2021 20:38:36
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User entered empty.	System	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User entered empty.	System	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User entered '0'	System	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57
User entered '1'	System	19 Apr 2021 20:38:36
User entered '0'	System	19 Apr 2021 20:33:55

US3222077

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:06:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:01:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:06:55

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:04
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:13:28
User closed query 'Per CDM: Response noted however, CM log line 14,15,17 are recorded for 'Kidney Stones', CM #16 for 'Urinary Tract Infection and CM#18 for 'Renal Pain Secondary to Kidney Stone'. Please note: there currently is no corresponding CM recorded that matches with Diary Dose 2 Day 7, Nausea/Vomiting (General)? Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per CDM: Response noted however, CM log line 14,15,17 are recorded for 'Kidney Stones', CM #16 for 'Urinary Tract Infection and CM#18 for 'Renal Pain Secondary to Kidney Stone'. Please note: there currently is no corresponding CM recorded that matches with Diary Dose 2 Day 7, Nausea/Vomiting (General)? Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'DOSE 2 DAY 7 WAS TREATED BECAUSE S/S WERE FROM KIDNEY STONE' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 14:18:46
Query 'Per CDM: Response noted however, CM log line 14,15,17 are recorded for 'Kidney Stones', CM #16 for 'Urinary Tract Infection and CM#18 for 'Renal Pain Secondary to Kidney Stone'. Please note: there currently is no corresponding CM recorded that matches with Diary Dose 2 Day 7, Nausea/Vomiting (General)? Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'DOSE 2 DAY 7 WAS TREATED BECAUSE S/S WERE FROM KIDNEY STONE' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:45:33
User opened query 'Per CDM: Response noted however, CM log line 14,15,17 are recorded for 'Kidney Stones', CM #16 for 'Urinary Tract Infection and CM#18 for 'Renal Pain Secondary to Kidney Stone'. Please note: there currently is no corresponding CM recorded that matches with Diary Dose 2 Day 7, Nausea/Vomiting (General)? Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:50:18
User closed query 'Per DM CLR: Per Diary Dose 2 Day 7, Nausea/Vomiting (General) = Prevents daily activity, requires outpatient IV hydration, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:50:18

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:06:55

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 7, Nausea/Vomiting (General) = Prevents daily activity, requires outpatient IV hydration, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'please review con med log line 14,15,16,17,18 as these are the corresponding meds given to subject for diary dose 2 day 7' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 14:24:33
User opened query 'Per DM CLR: Per Diary Dose 2 Day 7, Nausea/Vomiting (General) = Prevents daily activity, requires outpatient IV hydration, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.'	(b) (4), (b) (6)	25 Jan 2021 06:16:54
(Site from DM).		
User closed query 'Per DM CLR: Per Diary Dose 2 Day 8, Nausea/Vomiting (General) = Prevents daily activity, requires outpatient IV hydration, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.'	(b) (4), (b) (6)	15 Jan 2021 18:07:50
(Site from DM).		
Query 'Per DM CLR: Per Diary Dose 2 Day 8, Nausea/Vomiting (General) = Prevents daily activity, requires outpatient IV hydration, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.'	gail lavine (b) (4)	15 Jan 2021 15:28:10
' answered with 'no iv hydration reported by subject for this event' (Site from DM).	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:06:55

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 8, Nausea/Vomiting (General) = Prevents daily activity, requires outpatient IV hydration, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	04 Jan 2021 12:00:32
	(b) (4), (b) (6)	04 Nov 2020 21:13:51
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:24:00

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:27:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:27:56
Data point term sent to Coder	System	18 Sep 2020 16:27:06
User entered 'ALBUTEROL'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '90'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'ug (ug)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'as needed (PRN)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 2018'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 16:26:12

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: ALFUZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:13:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:13:36
Data point term sent to Coder	System	18 Sep 2020 16:30:14
User entered 'AFLUZOSIN'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'BENIGN PROSTATE HYPERPLASIA'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '10'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 2018'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:29:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:32:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:32:42
Data point term sent to Coder	System	18 Sep 2020 16:31:18
User entered 'ASPIRIN'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'CONGESTIVE HEART FAILURE'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '81'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'twice daily (BID)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 2000'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:31:08

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:12:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:12:37
Data point term sent to Coder	System	18 Sep 2020 16:33:24
User entered 'ATENOLOL'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'CONGESTIVE HEART FAILURE'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '25'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per CDM: response noted, however kindly verify both the dates on corresponding ConMed and MH pages and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 11:51:00
Query 'Per CDM: response noted, however kindly verify both the dates on corresponding ConMed and MH pages and update accordingly.' answered with 'updated in MH' (Site from DM).	gail lavine (b) (4) (b) (4)	01 Dec 2020 14:35:12
User opened query 'Per CDM: response noted, however kindly verify both the dates on corresponding ConMed and MH pages and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:47:28
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:47:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'Corrected date' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:19:38
User entered 'UN UNK 2018' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:19:08
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:10:48
User entered 'UN UNK 2008'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:32:49

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:37:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:37:15
Data point term sent to Coder	System	18 Sep 2020 16:35:28
User entered 'BREO ELLIPTA'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '100'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'ug (ug)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 12:43:49
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'Corrected year' (Site from DM).	(b) (4), (b) (6) douglas winter (b) (4) (b) (4)	04 Nov 2020 21:14:02 19 Oct 2020 17:21:17
User entered '01 Jan 2014' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:21:11
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). User entered '01 Jan 2013'	(b) (4), (b) (6) Crystal Paccione (b) (4) (b) (4)	19 Oct 2020 10:11:27 18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:34:33

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:37:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:37:18
Data point term sent to Coder	System	18 Sep 2020 16:36:34
User entered 'CETIRIZINE'	Crystal Paccione (b) (4)	18 Sep 2020 16:36:15
	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'SEASONAL ALLERGIES'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per DM CLR - Requery: Site's response noted. However, actual dosage for the medication given is needed instead of the tablet count. Review and update as applicable. Please update accordingly.Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 12:45:00
Query 'Per DM CLR - Requery: Site's response noted. However, actual dosage for the medication given is needed instead of the tablet count. Review and update as applicable. Please update accordingly.Update eCRF as appropriate. ' answered with 'DOSE UNIT IS INCORRECT AND SHOULD READ MG. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	13 Nov 2020 19:04:45
User opened query 'Per DM CLR - Requery: Site's response noted. However, actual dosage for the medication given is needed instead of the tablet count. Review and update as applicable. Please update accordingly.Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:16:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 02:16:02
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated dose' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:22:59
User entered '10' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:22:46
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:11:48

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
DataPoint Un-verified.	Albert Garcia (b) (4)	13 Nov 2020 19:04:56
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Albert Garcia (b) (4)	13 Nov 2020 19:04:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'tablet (TABLET)'	Crystal Paccione (b) (4)	18 Sep 2020 16:36:15
	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 1995'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:36:15

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:38:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:38:52
Data point term sent to Coder	System	18 Sep 2020 16:37:37
User entered 'FINASTERIDE'	Crystal Paccione (b) (4)	18 Sep 2020 16:37:34
	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'BENIGN PROSTATE HYPERPLASIA'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '5'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 2019'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:37:34

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:41:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:41:00
Data point term sent to Coder	System	18 Sep 2020 16:39:43
User entered 'LASIX'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'CONGESTIVE HEART FAILURE'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '20'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 2018'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:39:04

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:42:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:42:04
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 16:40:44
User entered 'LOVASTATIN'	Crystal Paccione (b) (4)	18 Sep 2020 16:40:43
	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'HYPERCHOLESTEROLEMIA'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '10'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 2010'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:40:43

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:43:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 16:43:55
Data point term sent to Coder	System	18 Sep 2020 16:42:45
User entered 'METFORMIN'	Crystal Paccione (b) (4)	18 Sep 2020 16:41:47
	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'DIABETES MELLITUS TYPE 2'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '500'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'twice daily (BID)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 2013' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:45:40
User entered 'UN UNK 2002'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:41:47

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:44:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:44:56
Data point term sent to Coder	System	18 Sep 2020 16:43:46
User entered 'MULTI VITAMIN'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'SUPPLEMENT'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'I'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'tablet (TABLET)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'UN UNK 2002'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:42:54

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:49:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:49:03
Data point term sent to Coder	System	18 Sep 2020 16:47:52
User entered 'POTASSIUM'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'SUPPLEMENT'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 11:35:05
User entered '10'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 11:13:01
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:35:21
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 11:35:05
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 11:28:32
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:12:18
User entered 'mg (mg)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '01 Jan 2018'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:47:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 16:52:48
Data point term sent to Coder	System	18 Sep 2020 16:52:04
User entered 'VITAMIN B COMPLEX' reason for change: Data Entry Error	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:51:17
Data point term sent to Coder	System	18 Sep 2020 16:51:00
User entered 'VITAMIN B COMPLES'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'SUPPLEMENT'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'I'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'tablet (TABLET)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once daily (QD)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'UN UNK 2002'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	Crystal Paccione (b) (4) (b) (4)	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:50:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 17:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 17:24:51
Data point term sent to Coder	System	01 Apr 2021 17:23:45
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 17:23:34
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 17:23:34
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 17:23:34
User entered 'OXYCONtin' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:23:34
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 22:21:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 22:21:45
Data point term sent to Coder	System	27 Sep 2020 16:41:24
User entered 'Oxycotin'	douglas winter (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Kidney stones'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '10'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'as needed (PRN)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	gail lavine (b) (4)	01 Dec 2020 14:44:29
	(b) (4)	
	Albert Garcia (b) (4)	10 Nov 2020 20:01:15
	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 20:01:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '18 Sep 2020'	douglas winter (b) (4)	27 Sep 2020 16:41:02
	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 09:51:02
' (Site from DM).		
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	01 Apr 2021 17:23:44
' answered with 'corrected' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 17:23:34
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 17:23:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:23:34
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	31 Mar 2021 03:48:43
' (Site from DM).		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:23:34
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 17:23:34
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:23:34
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User entered empty.	System	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User entered empty.	System	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:12
User entered empty.	System	27 Sep 2020 16:41:02

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
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)	25 Oct 2020 07:34:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:34:30
Data point term sent to Coder	System	19 Oct 2020 17:13:44
Coding entries removed.	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:13:12
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)	27 Sep 2020 22:16:44
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 Sep 2020 22:16:44
Data point term sent to Coder	System	27 Sep 2020 16:43:25
User entered 'Morphine drip'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 12:46:09
Query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' answered with 'UPDATED ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:53:32
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:53:23
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	14 Nov 2020 13:53:23
User opened query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 10:49:58
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Kidney stones'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per DM CLR: Please review and remove the unit from the dose field and provide the actual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 13:33:53
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
Query 'Per DM CLR: Please review and remove the unit from the dose field and provide the actual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:13:31
User entered '4' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:13:12
User opened query 'Per DM CLR: Please review and remove the unit from the dose field and provide the actual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:12:49
User entered 'mg'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'mg (mg)' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 17:13:12
User entered 'Other (OTHER)'	(b) (4) douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of DRIP count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 12:48:23
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
Query 'Per DM CLR: Please provide the actual dose for this medication instead of DRIP count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:13:34
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	19 Oct 2020 17:13:12
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of DRIP count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:12:57
User entered 'Drip'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	10 Nov 2020 20:01:46
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	10 Nov 2020 20:01:46
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	10 Nov 2020 20:01:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'once (ONCE)'	douglas winter (b) (4)	27 Sep 2020 16:42:57
	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 17:13:12
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Un-verified.	Albert Garcia (b) (4)	10 Nov 2020 20:01:26
User entered '15 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 20:01:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '18 Sep 2020'	douglas winter (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Un-verified.	Albert Garcia (b) (4)	10 Nov 2020 20:01:46
User entered '15 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 20:01:46
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '18 Sep 2020'	douglas winter (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User entered empty.	System	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User entered empty.	System	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:25:44
User entered empty.	System	27 Sep 2020 16:42:57

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIBIOTICS, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 22:26:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 22:26:19
User closed query 'Per DM CLR: Please provide brand/generic name if known. Or comment if if antibiotic therapy is unknown.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:23:24
Data point term sent to Coder	System	01 Dec 2020 15:46:05
Data point term sent to Coder	System	01 Dec 2020 15:30:48
User closed query 'CDM-Coding: Please specify the exact brand name or add "unknown" in brackets if it's unknown.' (Site from System).	System	01 Dec 2020 15:29:53
Query 'CDM-Coding: Please specify the exact brand name or add "unknown" in brackets if it's unknown.' answered with 'unknown' (Site from System).	gail lavine (b) (4)	01 Dec 2020 15:29:53
Data point term sent to Coder	System	01 Dec 2020 15:29:45
DataPoint Un-verified.	gail lavine (b) (4)	01 Dec 2020 15:29:41
User entered 'EMPIRIC ANTIBIOTIC THERAPY(unknown)' reason for change: Data Entry Error	gail lavine (b) (4)	01 Dec 2020 15:29:41
User opened query 'CDM-Coding: Please specify the exact brand name or add "unknown" in brackets if it's unknown.' (Site from System).	Coder Import (b) (4)	25 Nov 2020 07:17:03
Query 'Per DM CLR: Please provide brand/generic name if known. Or comment if if antibiotic therapy is unknown.' answered with 'THIS IS UNKNOWN. PLEASE ADVISE IF WE SHOULD INACTIVATE AS CONDITION IS UNKNOWN.' (Site from DM).	Albert Garcia (b) (4)	14 Nov 2020 13:52:54
User opened query 'Per DM CLR: Please provide brand/generic name if known. Or comment if if antibiotic therapy is unknown.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 07:36:11

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
Data point term sent to Coder	System	19 Oct 2020 16:54:06
User entered 'EMPIRIC ANTIBIOTIC THERAPY'	douglas winter (b) (4)	19 Oct 2020 16:53:14
	(b) (4)	

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Un-verified.	gail lavine (b) (4)	01 Dec 2020 15:44:35
User entered 'No (N)' reason for change: Data Entry Error	gail lavine (b) (4)	01 Dec 2020 15:44:35
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Yes (Y)'	douglas winter (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Un-verified.	gail lavine (b) (4)	01 Dec 2020 15:45:16
User entered 'urinary tract infection' reason for change: Data Entry Error	gail lavine (b) (4)	01 Dec 2020 15:45:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'EMPIRIC THERAPY'	douglas winter (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per CDM: As per CCG, If dose is unknown, kindly enter "UNK" into the text field and Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 08:24:01
Query 'Per CDM: As per CCG, If dose is unknown, kindly enter "UNK" into the text field and Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:02:35
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:02:22
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:02:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User opened query 'Per CDM: As per CCG, If dose is unknown, kindly enter "UNK" into the text field and Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:33:37
User entered 'UNKNOWN'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Other (OTHER)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'DOSE NOT PROVIDED'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'unknown (UNKNOWN)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '22 Sep 2020'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 16:53:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 16:53:20
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:20
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 16:53:14
User entered empty.	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '23 Sep 2020'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User entered empty.	System	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User entered empty.	System	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:11
User entered empty.	System	19 Oct 2020 16:53:14

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:11:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:11:30
Data point term sent to Coder	System	19 Oct 2020 16:57:09
User entered 'IV FLUIDS'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'KIDNEY STONES'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per CDM: As per CCG, If dose is unknown, kindly enter "UNK" into the text field and Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 12:51:40
Query 'Per CDM: As per CCG, If dose is unknown, kindly enter "UNK" into the text field and Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:03:01
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:02:56
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:02:56
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:14:02
User opened query 'Per CDM: As per CCG, If dose is unknown, kindly enter "UNK" into the text field and Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:36:45
User entered 'UNKNOWN'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Other (OTHER)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'DOSE IS UNKNOWN'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'unknown (UNKNOWN)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered empty.	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '22 Sep 2020'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '0'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered '23 Sep 2020'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User entered empty.	System	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User entered empty.	System	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:26:40
User entered empty.	System	19 Oct 2020 16:56:10

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
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)	13 Dec 2020 14:20:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Dec 2020 14:20:48
Data point term sent to Coder	System	01 Dec 2020 15:37:55
Data point term sent to Coder	System	01 Dec 2020 15:25:39
User entered 'morphine'	gail lavine (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'RENAL PAIN SECONDARY TO KIDNEY stone' reason for change: Data Entry Error	(b) (4) gail lavine (b) (4)	01 Dec 2020 15:37:24
User entered 'renal pain secondary to kidney'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '4'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'mg (mg)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'as needed (PRN)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '22 Sep 2020'	gail lavine (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '23 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	gail lavine (b) (4)	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User entered empty.	System	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User entered empty.	System	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:02
User entered empty.	System	01 Dec 2020 15:25:37

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:12:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:12:54
Data point term sent to Coder	System	10 Dec 2020 19:11:37
User entered 'Influenza'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Vaccine'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '.05'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'mL (mL)'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'once (ONCE)'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Intramuscular (INTRAMUSCULAR)'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered empty.	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '27 Oct 2020'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '0'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '27 Oct 2020'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'No (N)'	heather jackson (b) (4)	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User entered empty.	System	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User entered empty.	System	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:27:33
User entered empty.	System	10 Dec 2020 19:11:20

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONGESTIVE HEART FAILURE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 11:58:08
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONGESTIVE HEART FAILURE should be recorded, and update con med indication or provide clarification. ' answered with 'medication added as adjunct per md, chf hx stable with no changes' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:46:13
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONGESTIVE HEART FAILURE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:25:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 20:21:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 20:21:31
Data point term sent to Coder	System	26 Mar 2021 20:20:42
User entered 'lisinopril'	(b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'congestive heart failure'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '5'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:39:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:06:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Mar 2021 20:20:06

US3222077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:06:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:04
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	10 Nov 2020 19:53:05
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 15:55:58
	(b) (4)	

US3222077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '2 Oct 2020'	Albert Garcia (b) (4)	10 Nov 2020 19:53:43
	(b) (4)	

US3222077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:54:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:54:09
User entered 'LITHOTRIPSY' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 19:54:09
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:53:43
User entered empty.	Albert Garcia (b) (4)	10 Nov 2020 19:53:43
	(b) (4)	

US3222077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User closed query 'Per CDM: Indication is recorded as "Other" however KIDNEY STONES recorded for SAE # 1. Please review and update Indication accordingly. Else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 09:23:05
Query 'Per CDM: Indication is recorded as "Other" however KIDNEY STONES recorded for SAE # 1. Please review and update Indication accordingly. Else clarify' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	11 Dec 2020 14:00:31
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	11 Dec 2020 14:00:13
User opened query 'Per CDM: Indication is recorded as "Other" however KIDNEY STONES recorded for SAE # 1. Please review and update Indication accordingly. Else clarify' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 12:47:58
User entered 'Other (OTHER)'	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 19:53:43

US3222077

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:06:55

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	11 Dec 2020 14:00:13
	(b) (4)	
User entered 'SAE OF KIDNEY STONES'	Albert Garcia (b) (4)	10 Nov 2020 19:53:43
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	System	20 Oct 2020 14:05:34
	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry	douglas winter (b) (4)	20 Oct 2020 18:12:21
Error	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:06:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '28/Sep/2020 10:12'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'I'	(b) (4), (b) (6)	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered	System	28 Sep 2020 14:11:45
'USA-US104-2020-MRNA-1273-P301000004'		

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:06:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '30/Sep/2020 12:36'	System	30 Sep 2020 12:36:52

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:26:20
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 12:36:52

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:06:55

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '12/Oct/2020 13:26'	System	12 Oct 2020 13:26:33

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:30:29
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 13:26:33

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered	System	28 Sep 2020 14:11:45
'USA-US104-2020-MRNA-1273-P301000004'		

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:06:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '12/Oct/2020 13:30'	System	12 Oct 2020 17:30:36

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 15:53:39
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 17:30:36

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:06:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '13/Oct/2020 15:53'	System	13 Oct 2020 15:53:51

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 15:53:51

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:06:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '20/Oct/2020 14:05'	System	20 Oct 2020 14:05:34

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 14:05:34

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry	douglas winter (b) (4)	20 Oct 2020 18:12:21
Error	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:06:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '20/Oct/2020 13:48'	douglas winter (b) (4) (b) (4)	20 Oct 2020 17:52:57

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 14:00:11

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered	System	28 Sep 2020 14:11:45
'USA-US104-2020-MRNA-1273-P301000004'		

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	System	20 Oct 2020 14:05:34
	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry	douglas winter (b) (4)	20 Oct 2020 18:12:21
Error	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:06:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '21/Oct/2020 14:00'	System	21 Oct 2020 14:00:11

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 14:00:11

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered	System	28 Sep 2020 14:11:45
'USA-US104-2020-MRNA-1273-P301000004'		

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:06:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered '21/Oct/2020 17:33'	System	21 Oct 2020 17:34:01

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 14:55:50
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 17:34:01

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:06:55

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '11/Nov/2020 14:56'	(b) (4) System	11 Nov 2020 14:56:05

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 17:13:57
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 14:56:05

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered	System	28 Sep 2020 14:11:45
'USA-US104-2020-MRNA-1273-P301000004'		

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:06:55

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '02/Dec/2020 12:14'	(b) (4) System	02 Dec 2020 17:14:16

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:16:24
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 17:14:16

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

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Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:16:24
User entered '0'	(b) (4), (b) (6)	02 Dec 2020 17:14:16

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'USA-US104-2020-MRNA-1273-P301000004'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Yes (Y)'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'No (N)'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Teresa'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Lisa'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Tracy'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Bruce' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Tracy'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Tracy'	System	28 Sep 2020 14:11:45

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered 'Becker'	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Holloway'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered 'Kowalski'	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Rankin' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:45
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered 'Kowalski'	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
Un-reviewed for Safety.	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:12:24
User entered 'Kowalski'	System	28 Sep 2020 14:11:45

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '6550 Mapleridge Street'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '860 Peachwood Dr.' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '860 Peachwood Dr.'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'Houston'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Deland' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'DELAND'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Un-reviewed for Safety.	System	21 Dec 2020 15:17:09
User entered empty.	System	21 Dec 2020 15:17:09
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered 'TX'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered 'Florida' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered 'FL'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 15:16:24
Un-reviewed for Safety.	System	02 Dec 2020 17:14:16
DataPoint Un-verified.	System	02 Dec 2020 17:14:16
User entered '77081'	System	02 Dec 2020 17:14:16
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 17:31:48
Un-reviewed for Safety.	System	21 Oct 2020 14:00:11
User entered empty.	System	21 Oct 2020 14:00:11
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:59:56
User entered '32720' reason for change: Data Entry Error	douglas winter (b) (4)	20 Oct 2020 18:12:21
	(b) (4)	
Un-reviewed for Safety.	System	20 Oct 2020 14:05:34
User entered empty.	System	20 Oct 2020 14:05:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 14:05:21
User entered '32720'	douglas winter (b) (4)	19 Oct 2020 16:33:58
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:05:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 12:36:37
User entered 'US'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 16:06:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
	(b) (4)	
User entered '11'	System	21 Dec 2020 15:17:09
User entered '10'	System	02 Dec 2020 17:14:16
User entered '9'	System	11 Nov 2020 14:56:05
User entered '8'	System	21 Oct 2020 17:34:01
User entered '7'	System	21 Oct 2020 14:00:11
User entered '6'	System	20 Oct 2020 14:05:34
User entered '5'	System	13 Oct 2020 15:53:51
User entered '4'	System	12 Oct 2020 17:30:36
User entered '3'	System	12 Oct 2020 13:26:33
User entered '2'	System	30 Sep 2020 12:36:52
User entered '1'	System	28 Sep 2020 14:12:29

US3222077

Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 16:06:55

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered '21/Dec/2020 10:17'	(b) (4) System	21 Dec 2020 15:17:09

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Folder: SAE USA-US104-2020-MRNA-1273-P301000004

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 16:06:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:36:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:17:09