

US3062079 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:59:21

All time stamps listed in this document are displayed in GMT

US3062079

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:26:31

Generated On: 09 Jun 2021 14:59:21

Participant ID

US3062079

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

US3062079

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3062079

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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

US3062079

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 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

US3062079

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	IRRITABLE BOWEL SYNDROME- CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	MUSCLE SPASMS
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	NEUROPATHY, UNSPECIFIED BILATERAL HANDS
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3062079

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	BIPOLAR DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	NEPHROLITHIASIS, RECURRENT
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Condition	SMALL BOWEL OBSTRUCTION
Start date (dd MMM yyyy)	UN UNK 1995
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)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:28 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:28
Height (<i>xxx.x</i>)	163.0 cm
Weight (<i>xxx.x</i>)	99.6 kg
BMI (<i>xxx.x</i>)	37.48730 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) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 15:22:28

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Date of assessment (dd MMM yyyy) 04 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	04 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:22:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

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

Visit date (dd MMM yyyy)	04 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 101126

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) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

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) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

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)	04 AUG 2020
Time of assessment (00:00-23:59)	16:28 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:28
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

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)	04 AUG 2020
Time of assessment (00:00-23:59)	19:02 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 19:02
Temperature (xxx.x)	97.0 F
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)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

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) 04 AUG 2020

What was the treatment time? (00:00-23:59) 18:31 (24 HR)

Treatment Date and Time (derived) 04 AUG 2020 18:31

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) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 AUG 2020
Collection time (00:00-23:59)	17:37 (24 HR)
Collection date and time (derived)	04 AUG 2020 17:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:22	04 AUG 2020 17:22
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

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 14:59:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.0 °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 04 AUG 2020 19:06

PC Open Date & Time 04 AUG 2020 18:51

PC Close Date & Time 04 AUG 2020 21:21

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

04 AUG 2020 22:16

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

06 AUG 2020 02:38

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 12:02

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 18:41

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 19:21

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

09 AUG 2020 20:37

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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 21:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 19:07

PC Open Date & Time

04 AUG 2020 18:51

PC Close Date & Time

04 AUG 2020 21:21

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

04 AUG 2020 22:16

PC Close Date & Time

05 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 02:38

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

06 AUG 2020 12:02

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

07 AUG 2020 18:42

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

08 AUG 2020 19:22

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

09 AUG 2020 20:37

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

10 AUG 2020 21:18

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 19:08
PC Open Date & Time	04 AUG 2020 18:51
PC Close Date & Time	04 AUG 2020 21:21

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 AUG 2020 22:16

PC Close Date & Time

05 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 3460

EAB) (1725)

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 02:39
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 3460

EAB) (1725)

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 12:02
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

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 ☒

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 18:42
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

61 of 3460

EAB) (1725)

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:22
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

63 of 3460

EAB) (1725)

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:37
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

65 of 3460

EAB) (1725)

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 21:18
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3062079

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT	DAY 8
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 AUG 2020 20:01
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3062079

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

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)	04 SEP 2020
Time of assessment (00:00-23:59)	13:24 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 13:24
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

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)	04 SEP 2020
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:50
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3062079

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	04 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 14:19 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 14:19

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

US3062079

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	04 SEP 2020
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Collection time (00:00-23:59)	13:36 (24 HR)
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Collection date and time (derived)	04 SEP 2020 13:36
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US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:32	04 SEP 2020 13:32
Nasopharyngeal Swab 2	No		

US3062079

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

04 SEP 2020 14:54

PC Open Date & Time

04 SEP 2020 14:39

PC Close Date & Time

04 SEP 2020 17:09

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	04 SEP 2020 18:24
PC Open Date & Time	04 SEP 2020 18:04
PC Close Date & Time	05 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	05 SEP 2020 21:05
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

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

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

PC Time Stamp 06 SEP 2020 19:54

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 22:54

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

97.7 °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

08 SEP 2020 21:00

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 SEP 2020 21:21

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	11 SEP 2020 07:01
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 8

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	11 SEP 2020 20:14
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 21:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

04 SEP 2020 14:54

PC Open Date & Time

04 SEP 2020 14:39

PC Close Date & Time

04 SEP 2020 17:09

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 18:25

PC Open Date & Time

04 SEP 2020 18:04

PC Close Date & Time

05 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 21:05

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

06 SEP 2020 19:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

07 SEP 2020 22:54

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

08 SEP 2020 21:00

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

09 SEP 2020 21:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

11 SEP 2020 07:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 14:54
PC Open Date & Time	04 SEP 2020 14:39
PC Close Date & Time	04 SEP 2020 17:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 18:26
PC Open Date & Time	04 SEP 2020 18:04
PC Close Date & Time	05 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

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 ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:06
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

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 ☒

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:55
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 22:55
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

		Yes <input type="checkbox"/>
PC Time stamp	08 SEP 2020 21:00	
PC Open Date & Time	08 SEP 2020 12:00	
PC Close Date & Time	09 SEP 2020 11:59	

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

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 ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

		Yes <input type="checkbox"/>
PC Time stamp	09 SEP 2020 21:22	
PC Open Date & Time	09 SEP 2020 12:00	
PC Close Date & Time	10 SEP 2020 11:59	

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

	Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 07:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT	DAY 8
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 SEP 2020 20:15
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT	DAY 9
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	12 SEP 2020 21:30
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3062079

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:28

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	VISIT3

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:17 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 14:17
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

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.

US3062079

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	30 SEP 2020
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Collection time (00:00-23:59)	14:27 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	30 SEP 2020 14:27
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US3062079

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:22:29

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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	05 OCT 2020 19:59:12
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 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 05:31:24
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

22 OCT 2020 18:23:07

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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	01 NOV 2020 05:03:02
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 14:59:17

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 14:31:54

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 NOV 2020 20:48:51

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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	03 DEC 2020 06:19:01
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 16:49:55
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

28 DEC 2020 17:33:54

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 05:49:55
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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	18 JAN 2021 20:47:35
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 20:06:43

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 04:12:25

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

Date and time of submission

04 FEB 2021 06:45:05

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 08:08:24

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 09:02:32

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 10:10:14

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 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 MAR 2021 16:30:29
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 09:01:50

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 16:39:08

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

Date and time of submission

29 MAR 2021 16:55:49

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 13:40:41

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 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	08 APR 2021 07:36:12
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 11:22:47

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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	23 APR 2021 10:36:19
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 10:03:54

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 <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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 <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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 <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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 <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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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°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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 <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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 <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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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="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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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 ☐

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3062079

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:59:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 16:30:14

US3062079

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 20:55:29

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 20:55:29

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

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

Visit date (dd MMM yyyy)	10 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:10 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 10:10
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

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.

US3062079

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 10 MAR 2021

Collection time (00:00-23:59) 10:15 (24 HR)

Collection date and time (derived) 10 MAR 2021 10:15

US3062079

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3062079

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062079

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

US3062079

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3062079

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:59:21

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"/>

US3062079

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:59:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3062079

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:26:40

Generated On: 09 Jun 2021 14:59:21

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

Visit date (dd MMM yyyy)	26 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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US3062079

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:26:40

Generated On: 09 Jun 2021 14:59:21

Date of updated informed consent (*dd MMM yyyy*) 26 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*) 26 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 _____

US3062079

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:26:40

Generated On: 09 Jun 2021 14:59:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

16:35 (24 HR)

Collection date and time (derived)

26 JAN 2021 16:35

US3062079

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:26:40

Generated On: 09 Jun 2021 14:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00 - 23:59)	16:37
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Collection Date and Time (derived)	26 JAN 2021 16:37
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US3062079

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 20:55:29

Generated On: 09 Jun 2021 14:59:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID	USA-US090-2020-MRNA-1273-P30 1000001
Adverse event	WORSENING OF NEPHROLITHIASIS RECURRENT
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)	07 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)	10 SEP 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)	07 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	10 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	338 of 3460

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

SUBJECT PRESENTED TO
EMERGENCY ROOM 9/7/2020
FOR ABDOMINAL PAIN.
SUBJECT REPORTED HISTORY
OF RECURRENT
NEPHROLITHIASIS. SHE ALSO
REPORTED THAT SHE HAD A
HISTORY OF SMALL BOWEL
OBSTRUCTION AS A
TEENAGER. SUBJECT
UNDERWENT CT OF ABDOMEN
AND PELVIS WITH CONTRAST
DURING VISIT TO EMERGENCY
ROOM. THE CT SHOWED
BILATERAL NEPHROLITHIASIS
WITH A PARTIALLY
OBSTRUCTING 8MM RIGHT
URETEROPELVIC JUNCTION
STONE. SUBJECT WAS
ADMITTED TO THE HOSPITAL
FOR PAIN CONTROL ON 9/7/2020
AND SURGERY WAS PLANNED
FOR 9/9/2020. ON 9/9/2020,
SUBJECT UNDERWENT A
CYSTOSCOPY AND RIGHT
URETEROSCOPY WITH LASER
LITHOTRIPSY. A RIGHT RENAL
STENT WAS ALSO PLACED AT
TIME.

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

US3062079

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID

Adverse event

POST OP PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 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)

16 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

341 of 3460

EAB) (1725)

US3062079

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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 _____ _____	
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)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

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AEID

Adverse event

RIGHT OBSTRUCTING
URETERAL STONE

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)

07 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)

09 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 ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
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	
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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID	
Adverse event	RIGHT HYDRONEPHROSIS
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)	07 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID	
Adverse event	TRANSMINITIS
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)	07 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID	USA-US090-2021-MRNA-1273-P30 1000007
Adverse event	WORSENING OF RECURRENT NEPHROLITHIASIS
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)	3 NOV 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)	11 DEC 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)	10 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	11 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 11:58:18

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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 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	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 11:58:18

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SUBJECT STATED A RECENT HOSPITALIZATION DURING THE UNBLINDING VISIT ON 1/26/2021. SUBJECT STATED SHE WENT TO ER WITH ABDOMINAL PAIN AND WAS NOTED TO HAVE A URETERAL STONE ON 11/3/2020. SUBJECT HAD STENT PLACED AND LITHOTRIPSY. THESE METHODS FAILED TO DRAIN THE STONE. SUBJECT HAD A PLANNED PERCUTANEOUS NEPHROSTOLITHOTOMY ON 12/10/2021. THE SUBJECT WAS OBSERVED OVERNIGHT AND RELEASED WITHOUT COMPLICATIONS THE FOLLOWING DAY ON 12/11/2020. RECORDS REQUESTED FOR ANY ADDITIONAL INFORMATION. IF NEW INFORMATION BECOMES AVAILABLE, A FU REPORT WILL BE COMPLETED. 3/22/2021 RECEIVED MEDICAL RECORDS FOR SUBJECT'S HOSPITAL STAY. SUBJECT HAD A DOUBLE J STENT PLACED IN SUBJECT'S LEFT KIDNEY ON 11/3/2021. SUBJECT ALSO HAD A LITHOTRIPSY TO BREAK STONE INTO SMALLER PIECES. DOCTOR'S NOTES STATES IF

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 11:58:18

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SUBJECT HAS SIGNIFICANT
STONE BURDEN THEN SHE
WILL NEED A PCNL, SUBJECT
HAS NOT REPORTED HAVING
THAT PROCEDURE DONE SINCE
SHE HAD THIS PROCEDURE
DONE. PRIOR TO PROCEDURE
SUBJECT HAD SIGNIFICANT
PAIN AND RECEIVED
MULTIPLE PAIN MEDICATION
TO ASSIST IN CONTROLLING
PAIN. SUBJECT RECEIVED IV
MEDS PRIOR TO PROCEDURE.
SUBJECT DID NOT HAVE ANY
MEDICATIONS PRESCRIBED
WHEN BEING DISCHARGED
FROM THE HOSPITAL.

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID	
Adverse event	PAIN- GENERALIZED
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)	3 NOV 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)	3 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 11:58:18

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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 _____ _____	
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)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID

Adverse event

NAUSEA- GENERALIZED

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)

3 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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 _____	
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)	_____

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID

Adverse event

BLADDER CALCULUS

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)

3 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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	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)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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)

3 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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 _____	
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)	_____

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

AEID USA-US090-2021-MRNA-1273-P30
1000012

Adverse event WORSENING OF RECURRENT
NEPHROLITHIASIS

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) 19 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☒

Is the adverse event serious? Yes ☒
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 19 APR 2021

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☒
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3062079

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

SUBJECT WAS CONTACTED TO
COMPLETE WEEKLY DIARY,
SITE LEFT MESSAGE FOR
SUBJECT. SUBJECT RETURNED
CALL TO INFORM SITE THAT
SHE IS ADMITTED TO NMC
HEALTH HOSPITAL FOR
WORSENING OF RECURRENT
NEPHROLITHIASIS. SUBJECT
BEGAN HAVING FLANK PAIN
AND WENT TO THE
EMERGENCY ROOM WHERE
SHE WAS DIAGNOSED WITH
NEPHROLITHIASIS. SHE WAS
ADMITTED AND HAD A
LITHOTRIPSY PERFORMED ON
4/21/2021. WHEN SITE STAFF
SPOKE TO SUBJECT, SHE
REPORTED THAT THERE IS A
POSSIBILITY OF DISCHARGE
4/23/2021. RELEASE OF
RECORDS SENT TO SUBJECT TO
BE SIGNED AND RETURNED.

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

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 13:20:05

Generated On: 09 Jun 2021 14:59:21

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

Yes ☒

No ☐

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

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication EQUATE STOOL SOFTENER

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL
SYNDROME- CONSTIPATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	UN UNK 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 (2)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY-BILATERAL
HANDS, UNSPECIFIED

Dose per administration 300

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	UN JAN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication MICROGESTIN FE 1/20

Prophylaxis Yes ☐
No ☒

Indication CONTRACEPTION

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 (3)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 (4)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 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)	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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication VIIBRYD

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DEPRESSION

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 (5)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 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)	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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication INDERAL

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

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 (6)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 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)	3	
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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication LAMICTAL

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 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)	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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 15

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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 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 (9)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication FLEXERIL

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SPASMS LEGS

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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 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 (10)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL 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 (10)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

Dose per administration 1000

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 (11)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		07 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) 07 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 (12)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication NORCO 5/325MG

Prophylaxis Yes ☐
No ☒

Indication POST OP PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		09 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) 16 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 (13)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication COMPAZINE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		07 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) 07 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 (14)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE/ HOUR

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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		07 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)		10 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 (15)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

Dose per administration 0.4

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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		07 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) 10 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

Dose per administration 2

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 (16)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		07 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)		10 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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication NORCO 5/325MG

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

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 (17)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		07 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) 09 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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication SENNOSIDES/DOCUSATE
SODIUM (8.6MG/50MG)

Prophylaxis Yes ☐
No ☒

Indication IBS- CONSTIPATION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	07 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)	10 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

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 (19)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		09 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)		09 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 (20)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication IBS- CONSTIPATION

Dose per administration 17

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) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 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) _____		
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 (21)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 10 SEP 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication KEFZOL

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

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 (22)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		09 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)		09 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication OMNIPAQUE

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

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 (23)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		09 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)		09 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 600

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 (24)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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 (25)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication LACTATED RINGER'S SOLUTION

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	09 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)		09 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 (26)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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 (26)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		05 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)		11 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (27)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication ABILIFY

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DEPRESSION

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 (27)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	13 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication ABILIFY

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DEPRESSION

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 (28)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication NORCO

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

Dose per administration 5/325

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 (29)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 DEC 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 (30)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL NEPHROLITHIASIS

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 (30)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		7 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) 7 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 (31)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

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 (31)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 15:18:51

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Name of Medication XYLOCAINE(1%)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

Dose per administration 0.2

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 (32)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (33)

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Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

Dose per administration 1000

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

150 ML PER HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

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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 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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (34)

Data signed: (b) (4) 16 Apr 2021 15:18:51

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Name of Medication	VERSED
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	WORSENING OF RECURRENT NEPHROLITHIASIS
Dose per administration	2
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (35)

Data signed: (b) (4) 16 Apr 2021 15:18:51

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Name of Medication SCOPOLAMINE

Prophylaxis Yes ☐
No ☒

Indication NAUSEA, GENERALIZED

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

ONCE EVERY 3 DAYS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

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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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 NOV 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 (36)

Data signed: (b) (4) 16 Apr 2021 15:18:51

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Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA- GENERALIZED

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 (36)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (37)

Data signed: (b) (4) 16 Apr 2021 15:18:51

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Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

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)

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	Intraocular	<input type="radio"/>
	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (38)

Data signed: (b) (4) 16 Apr 2021 15:18:51

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Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication URINARY TRACT INFECTION

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 (38)

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	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (39)

Data signed: (b) (4) 16 Apr 2021 15:18:51

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Name of Medication SUXAMETHONIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

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 (39)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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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Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 16 Apr 2021 15:18:51

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Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication PAIN- GENERALIZED

Dose per administration 250

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 (40)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (41)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication PROPOFOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (42)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

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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 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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (43)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

Dose per administration 1000

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

125 ML PER HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (44)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication DEMEROL

Prophylaxis Yes ☐
No ☒

Indication PAIN- GENERALIZED

Dose per administration 12.5

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 (44)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (45)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication BELLADONNA-OPIMUM

Prophylaxis Yes ☐
No ☒

Indication PAIN GENERALIZED

Dose per administration 30/16.2

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 (45)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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 checked="" 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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (46)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication HEPARIN LOCK

Prophylaxis Yes ☐
No ☒

Indication IV PATENCY

Dose per administration 500

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

If dose unit is Other, specify UNITS

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 (46)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (47)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication PAIN GENERALIZED

Dose per administration 5/325

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 (47)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 NOV 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 (48)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication PAIN GENERALIZED

Dose per administration 2

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 (48)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (49)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication DITROPAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RECURRENT
NEPHROLITHIASIS

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 (49)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 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 (50)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA- GENERALIZED

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 (50)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	Intramuscular	<input 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 checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUALLY	
Start date (dd MMM yyyy)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	3 NOV 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 (51)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication PAIN- GENERALIZED

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

	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)		3 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 NOV 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"/>

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:26:40

Generated On: 09 Jun 2021 14:59:21

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) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 SEP 2020	RIGHT URETEROSCOPY WITH LASER LITHOTRIPSY	Adverse Event	
09 SEP 2020	PLACEMENT OF RENTAL STENT	Adverse Event	
07 SEP 2020	CT ABDOMEN/PELVIS WITH CONTRAST	Adverse Event	
03 NOV 2020	URETERAL STENT	Adverse Event	
3 NOV 2020	LITHOTRIPSY	Adverse Event	
10 DEC 2020	PERCUTANEOUS NEPHROLITHOTOMY	Adverse Event	
21 APR 2021	LITHOTRIPSY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:59:21

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 14:59:21

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 ☐

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Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2020-MRNA-1273-P301000001
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

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Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2020-MRNA-1273-P301000001
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/SEP/2020 17:15
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

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2020-MRNA-1273-P301000001
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/SEP/2020 08:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2020-MRNA-1273-P301000001
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:05
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

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 20:26:41

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2020-MRNA-1273-P301000001
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/OCT/2020 18:17
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

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000007
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000007
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	28/JAN/2021 14:03
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

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000007
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/FEB/2021 10:08
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

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000007
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/MAR/2021 10:52
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

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000007
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/MAR/2021 06:45
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

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000007
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/APR/2021 13:00
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

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 15:18:51

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000007
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/APR/2021 13:40
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

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000012
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 11:58:18

Generated On: 09 Jun 2021 14:59:21

SAEID	USA-US090-2021-MRNA-1273-P301000012
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	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	26/APR/2021 10:01
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

US3062079 (Prod: Alliance for Multispecialty Research, LLC)

US3062079

Form: Participant Creation

Generated On: 09 Jun 2021 14:59:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'US3062079'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 21:19:26

US3062079

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:42:55

US3062079

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 21:19:27

US3062079

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Clinic (Clinic)'	Riley King (b) (4)	04 Aug 2020 23:42:55
	(b) (4)	

US3062079

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'SCRN'	System	04 Aug 2020 23:42:55

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered (b) (6) 1979'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 21:19:28

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '40'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24
	(b) (4)	

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'YEARS'	System	06 Aug 2020 00:03:24

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '40'	System	04 Aug 2020 23:43:28

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Female (F)'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:03:24
	(b) (4)	

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'I'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24
	(b) (4)	

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24
	(b) (4)	

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4)	06 Aug 2020 00:03:24
	(b) (4)	

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24
	(b) (4)	

US3062079

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:59:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:03:24

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Aug 2020'	Riley King (b) (4)	04 Aug 2020 23:43:28
	(b) (4)	

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Aug 2020'	System	04 Aug 2020 23:43:28

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '2020'	System	04 Aug 2020 23:43:28

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Amendment 1 (1)'	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:43:28

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 23:43:28
	(b) (4)	

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:43:28

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:43:28

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 23:43:28
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 21:19:27

US3062079

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:59:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'I'	System	04 Aug 2020 23:43:33

US3062079

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 23:43:33
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:59:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:54:07
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Constipation predominant irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:50:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 13:50:29
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 23:55:25
User entered 'IRRITABLE BOWEL SYNDROME-CONSTIPATION'	Janna Martinez (b) (4)	05 Aug 2020 23:55:15
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	08 Aug 2020 00:37:46
User entered 'un UNK 2019' reason for change: Data Entry Error	Sherry Henning (b) (4)	08 Aug 2020 00:37:46
	(b) (4)	
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	05 Aug 2020 23:55:15
User entered empty.	Janna Martinez (b) (4)	05 Aug 2020 23:55:15
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:55:15
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:55:15
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:55:15
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:55:15

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 2019'	System	08 Aug 2020 00:37:46
User entered empty.	System	05 Aug 2020 23:55:15

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '2019'	System	08 Aug 2020 00:37:46
User entered empty.	System	05 Aug 2020 23:55:15

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:55:15

US3062079

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:55:15

US3062079

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Aug 2020 23:57:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:57:10
Data point term sent to Coder	System	05 Aug 2020 23:56:26
User entered 'MUSCLE SPASMS'	Janna Martinez (b) (4)	05 Aug 2020 23:55:52
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'UN UNK 1998'	Janna Martinez (b) (4)	05 Aug 2020 23:55:52
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:55:52

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:55:52

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:55:52
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:55:52

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 1998'	System	05 Aug 2020 23:55:52

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '1998'	System	05 Aug 2020 23:55:52

US3062079

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:55:52

US3062079

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:55:52

US3062079

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 13:21:56
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 13:21:56
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). 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)	08 Sep 2020 06:26:17
Data point term sent to Coder	System	04 Sep 2020 23:02:29
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). 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 corrected' (Site from DM).	Janna Martinez (b) (4)	04 Sep 2020 23:01:58
Coding entries removed.	Janna Martinez (b) (4)	04 Sep 2020 23:01:47
User entered 'NEUROPATHY, unspecified BILATERAL HANDS' reason for change: Data Entry Error	Janna Martinez (b) (4)	04 Sep 2020 23:01:47
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor). 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)	01 Sep 2020 06:46:30
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 00:34:14

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4)	18 Aug 2020 00:34:14
User entered 'NEUROPATHY, BILATERAL HANDS'	(b) (4) System	05 Aug 2020 23:57:26
	Janna Martinez (b) (4)	05 Aug 2020 23:56:49
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'UN UNK 2017'	Janna Martinez (b) (4)	05 Aug 2020 23:56:49

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) Janna Martinez (b) (4) (b) (4)	05 Aug 2020 23:56:49

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:56:49
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:56:49
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:56:49
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 2017'	System	05 Aug 2020 23:56:49

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '2017'	System	05 Aug 2020 23:56:49

US3062079

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:56:49

US3062079

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:56:49

US3062079

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:58:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:58:07
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 23:57:26
User entered 'INSOMNIA'	Janna Martinez (b) (4)	05 Aug 2020 23:57:07
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'UN UNK 2013'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:57:07
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:57:07
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:57:07
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:57:07
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:57:07
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 2013'	System	05 Aug 2020 23:57:07

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '2013'	System	05 Aug 2020 23:57:07

US3062079

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:57:07

US3062079

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:57:07

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar depression - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:59:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:59:08
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 23:58:27
User entered 'BIPOLAR DEPRESSION'	Janna Martinez (b) (4)	05 Aug 2020 23:57:30
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'UN UNK 2013'	Janna Martinez (b) (4)	05 Aug 2020 23:57:30

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:57:30

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:57:30
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:57:30
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:57:30
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 2013'	System	05 Aug 2020 23:57:30

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '2013'	System	05 Aug 2020 23:57:30

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:57:30

US3062079

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:57:30

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:59:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 23:59:07
Data point term sent to Coder	System	05 Aug 2020 23:58:27
User entered 'ANXIETY'	Janna Martinez (b) (4)	05 Aug 2020 23:57:42
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'UN UNK 2013'	Janna Martinez (b) (4)	05 Aug 2020 23:57:42
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	05 Aug 2020 23:57:42
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	Janna Martinez (b) (4)	05 Aug 2020 23:57:42

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:57:42
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:57:42
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 2013'	System	05 Aug 2020 23:57:42

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '2013'	System	05 Aug 2020 23:57:42

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:57:42

US3062079

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	05 Aug 2020 23:57:42

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 23:04:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 23:04:46
Data point term sent to Coder	System	04 Sep 2020 23:04:32
User entered 'migraines'	Janna Martinez (b) (4) (b) (4)	04 Sep 2020 23:04:12

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'un UNK 2000'	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 23:04:12
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 23:04:12
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 23:04:12
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 23:04:12

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	Janna Martinez (b) (4)	04 Sep 2020 23:04:12
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 2000'	System	04 Sep 2020 23:04:12

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '2000'	System	04 Sep 2020 23:04:12

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	04 Sep 2020 23:04:12

US3062079

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	04 Sep 2020 23:04:12

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis recurrent - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	25 Sep 2020 06:02:42
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:02:42
Data point term sent to Coder	System	24 Sep 2020 20:48:42
User entered 'nephrolithiasis, recurrent'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:48:06

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'un UNK 1998'	(b) (4) marissa Mueller (b) (4)	24 Sep 2020 20:48:06
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4)	24 Sep 2020 20:48:06
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	24 Sep 2020 20:48:06
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	24 Sep 2020 20:48:06
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4)	24 Sep 2020 20:48:06
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 1998'	System	24 Sep 2020 20:48:06

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '1998'	System	24 Sep 2020 20:48:06

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	24 Sep 2020 20:48:06

US3062079

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	24 Sep 2020 20:48:06

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
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.	(b) (4) Coder Import (b) (4)	13 Oct 2020 01:12:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 01:12:26
Data point term sent to Coder	System	13 Oct 2020 01:11:24
User entered 'seasonal allergies'	marissa Mueller (b) (4)	13 Oct 2020 01:10:44
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'un UNK 1985'	(b) (4) marissa Mueller (b) (4)	13 Oct 2020 01:10:44
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	13 Oct 2020 01:10:44
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	13 Oct 2020 01:10:44
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	13 Oct 2020 01:10:44
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4)	13 Oct 2020 01:10:44
	(b) (4)	

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 1985'	System	13 Oct 2020 01:10:44

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '1985'	System	13 Oct 2020 01:10:44

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	13 Oct 2020 01:10:44

US3062079

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	13 Oct 2020 01:10:44

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	20 Oct 2020 20:57:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:57:40
Data point term sent to Coder	System	20 Oct 2020 20:56:44
User entered 'Small Bowel Obstruction'	Jeri King (b) (4)	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'un UNK 1995'	(b) (4) Jeri King (b) (4)	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Jeri King (b) (4)	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)'	Jeri King (b) (4)	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'un UNK 1995'	Jeri King (b) (4)	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	Jeri King (b) (4)	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 1995'	System	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '1995'	System	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'Jan 1995'	System	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '1995'	System	20 Oct 2020 20:56:37

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '04 Aug 2020'	Janna Martinez (b) (4)	05 Aug 2020 23:59:59

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '16:28'	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered '04 Aug 2020 16:28'	System	05 Aug 2020 23:59:59

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '163.0' cm	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
DataPoint set to visible.	System	04 Aug 2020 23:43:33

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '99.6' kg	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
DataPoint set to visible.	System	04 Aug 2020 23:43:33

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
Amendment Manager: User entered '37.48730'	System	16 Sep 2020 23:43:16
User entered '37.5'	System	05 Aug 2020 23:59:59
DataPoint set to visible.	System	04 Aug 2020 23:43:33

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'kg/m2'	System	05 Aug 2020 23:59:59
DataPoint set to visible.	System	04 Aug 2020 23:43:33

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:06
User entered '98.1' F	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:06
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:06
User entered '85'	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'bpm'	System	05 Aug 2020 23:59:59

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:06
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'breaths/min'	System	05 Aug 2020 23:59:59

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:06
User entered '127'	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

US3062079

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'mmHg'	System	05 Aug 2020 23:59:59

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:06
User entered '86'	(b) (4)	
	Janna Martinez (b) (4)	05 Aug 2020 23:59:59
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered 'mmHg'	System	05 Aug 2020 23:59:59

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56

US3062079

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:27
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:02:14
	(b) (4)	

US3062079

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	06 Sep 2020 13:16:53
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		04 Sep 2020 19:23:31
User entered '04 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:27
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:02:14
	(b) (4)	

US3062079

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Aug 2020'	marissa Mueller (b) (4)	02 Sep 2020 14:00:48
	(b) (4)	

US3062079

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:21

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:00:48
	(b) (4)	

US3062079

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:00:48
	(b) (4)	

US3062079

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:00:48
	(b) (4)	

US3062079

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:00:48
	(b) (4)	

US3062079

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:21

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '0'	marissa Mueller (b) (4)	02 Sep 2020 14:00:48
	(b) (4)	

US3062079

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:00:48
	(b) (4)	

US3062079

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:59:21

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:00:48
	(b) (4)	

US3062079

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:57
	(b) (4)	

US3062079

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Aug 2020'	marissa Mueller (b) (4)	02 Sep 2020 14:01:57
	(b) (4)	

US3062079

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Urine (URINE)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:57
	(b) (4)	

US3062079

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Negative (NEGATIVE)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:57
	(b) (4)	

US3062079

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	02 Sep 2020 14:01:57
	(b) (4)	

US3062079

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:57
	(b) (4)	

US3062079

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:57
	(b) (4)	

US3062079

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User entered empty.	System	02 Sep 2020 14:01:57

US3062079

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

US3062079

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

US3062079

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

US3062079

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

US3062079

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

US3062079

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

[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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

US3062079

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

US3062079

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

[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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4) (b) (4)	02 Sep 2020 14:01:37

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	02 Sep 2020 14:01:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	02 Sep 2020 14:01:37

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'I'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	02 Sep 2020 14:01:37

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4) (b) (4)	02 Sep 2020 14:01:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '0'	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:59:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:25:56
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) marissa Mueller (b) (4)	02 Sep 2020 14:01:37
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 23:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Aug 2020'	Riley King (b) (4)	04 Aug 2020 23:43:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Clinic (Clinic)'	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:43:50

US3062079

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'VISIT1'	System	04 Aug 2020 23:43:50

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 22:44:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:07:33
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:07:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 22:44:10
User entered '101126' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 22:44:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 22:44:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:44:08

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:44:08

US3062079

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 23:44:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	04 Aug 2020 23:44:08
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:59:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:44:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:16
	(b) (4)	
User entered '163.0' cm	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:16
	(b) (4)	
User entered '99.6' kg	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:16
	(b) (4)	
User entered '163.0' cm	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:16
	(b) (4)	
User entered '99.6' kg	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Aug 2020'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '16:28'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered '04 Aug 2020 16:28'	System	06 Aug 2020 00:24:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '98.1' F	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:24:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '85'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'bpm'	System	06 Aug 2020 00:24:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'breaths/min'	System	06 Aug 2020 00:24:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '127'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'mmHg'	System	06 Aug 2020 00:24:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '86'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'mmHg'	System	06 Aug 2020 00:24:44

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:16
	(b) (4)	
User entered '163.0' cm	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:59:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:16
	(b) (4)	
User entered '99.6' kg	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Aug 2020'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
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) (6)	12 Aug 2020 06:27:40
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'DATA CORRECT AS ENTERED' (Site from System).	Janna Martinez (b) (4)	06 Aug 2020 00:25:17
	(b) (4)	
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).		06 Aug 2020 00:24:44
User entered '19:02'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered '04 Aug 2020 19:02'	System	06 Aug 2020 00:24:44

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User closed query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	System	06 Aug 2020 00:25:00
Query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' answered by data change (Site from System).	System	06 Aug 2020 00:25:00
User entered '97.0' F reason for change: Data Entry Error	Janna Martinez (b) (4)	06 Aug 2020 00:25:00
	(b) (4)	
User opened query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	System	06 Aug 2020 00:24:44
User entered '97.0' C	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '88'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'bpm'	System	06 Aug 2020 00:24:44

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '19'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'breaths/min'	System	06 Aug 2020 00:24:44

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '116'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'mmHg'	System	06 Aug 2020 00:24:44

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '84'	Janna Martinez (b) (4)	06 Aug 2020 00:24:44
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'mmHg'	System	06 Aug 2020 00:24:44

US3062079

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:34
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:25:32
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 19:24:34
	(b) (4)	
User entered '4 Aug 2020'	Janna Martinez (b) (4)	06 Aug 2020 00:25:32
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User closed query ' Per CDM: When Screening and Visit 1 Day 1 occur on the same day, the corresponding field at Visit 1 Day 1 should be marked as "No" and pregnancy test data should not be recorded on this page. Please review and update Visit 1 Day 1 as appropriate.' (Site from DM).	(b) (4)	18 Sep 2020 09:57:56
Query ' Per CDM: When Screening and Visit 1 Day 1 occur on the same day, the corresponding field at Visit 1 Day 1 should be marked as "No" and pregnancy test data should not be recorded on this page. Please review and update Visit 1 Day 1 as appropriate.' answered with 'updated per query' (Site from DM).	marissa Mueller (b) (4)	17 Sep 2020 17:09:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 17:09:29
User opened query ' Per CDM: When Screening and Visit 1 Day 1 occur on the same day, the corresponding field at Visit 1 Day 1 should be marked as "No" and pregnancy test data should not be recorded on this page. Please review and update Visit 1 Day 1 as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:27:35
User entered 'Yes (Y)'	Sherry Henning (b) (4)	16 Sep 2020 20:36:00

US3062079

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty; reason for change Data Entry Error	(b) (4) marissa Mueller (b) (4)	17 Sep 2020 17:09:29
User entered '4 Aug 2020'	(b) (4) Sherry Henning (b) (4)	16 Sep 2020 20:36:00

US3062079

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	17 Sep 2020 17:09:29
	(b) (4)	
User entered 'Urine (URINE)'	Sherry Henning (b) (4)	16 Sep 2020 20:36:00
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	17 Sep 2020 17:09:29
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Sherry Henning (b) (4)	16 Sep 2020 20:36:00
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User closed query 'Per CDM: Please respond to this question as the field is not to be left empty. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 08:54:16
Query 'Per CDM: Please respond to this question as the field is not to be left empty. Thank you.' answered with 'updated per query' (Site from DM).	marissa Mueller (b) (4) (b) (4)	25 Sep 2020 17:13:12
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	25 Sep 2020 17:13:07
User opened query 'Per CDM: Please respond to this question as the field is not to be left empty. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:09:00
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4) (b) (4)	17 Sep 2020 17:09:29
User entered 'No (N)'	Sherry Henning (b) (4) (b) (4)	16 Sep 2020 20:36:00

US3062079

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	Sherry Henning (b) (4)	16 Sep 2020 20:36:00

US3062079

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty; reason for change Data Entry Error	(b) (4) marissa Mueller (b) (4)	17 Sep 2020 17:09:29
Query 'Per CDM: Was FSH sample collected? = No. Per CCGs page 24 only if 'Yes' is selected, the date and time of FSH collection is to be recorded in these fields. Please review and update accordingly.'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 12:50:28
canceled (Site from DM).		
User opened query 'Per CDM: Was FSH sample collected? = No. Per CCGs page 24 only if 'Yes' is selected, the date and time of FSH collection is to be recorded in these fields. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:47:51
User entered '17:05'	Sherry Henning (b) (4) (b) (4)	16 Sep 2020 20:36:00

US3062079

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered empty.	System	16 Sep 2020 20:36:00

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	04 Aug 2020 23:44:33
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Riley King (b) (4)	04 Aug 2020 23:44:33
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	04 Aug 2020 23:44:33

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 23:44:33

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Aug 2020'	Riley King (b) (4)	04 Aug 2020 23:44:33
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '18:31'	Riley King (b) (4)	04 Aug 2020 23:44:33
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered '04 Aug 2020 18:31'	System	04 Aug 2020 23:44:33

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Riley King (b) (4)	04 Aug 2020 23:44:33
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'ONCE'	System	04 Aug 2020 23:44:33

US3062079

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 23:44:33

US3062079

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:26:07
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Aug 2020'	Janna Martinez (b) (4)	06 Aug 2020 00:26:07
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '17:37'	Janna Martinez (b) (4)	06 Aug 2020 00:26:07

US3062079

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered '04 Aug 2020 17:37'	System	06 Aug 2020 00:26:07

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:59:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '04 Aug 2020'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:26:26
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Janna Martinez (b) (4)	06 Aug 2020 00:26:26
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:26:26
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '17:22'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:26:26
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered '04 Aug 2020 17:22'	System	06 Aug 2020 00:26:26

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Janna Martinez (b) (4)	06 Aug 2020 00:26:26
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'No (N)'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:26:26
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:26:26
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered empty.	System	06 Aug 2020 00:26:26

US3062079

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	06 Aug 2020 00:26:31
	(b) (4)	

US3062079

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User entered 'I'	System	06 Aug 2020 00:26:31

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:06:42', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c16b56b3-ca0a-4ca9-99cc-4c551229e14d'	System	05 Aug 2020 00:07:04
User entered 'Yes (Y)'	System	05 Aug 2020 00:07:04

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:06:46', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c16b56b3-ca0a-4ca9-99cc-4c551229e14d'	System	05 Aug 2020 00:07:04
User entered '97.0'	System	05 Aug 2020 00:07:04

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:06:51', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c16b56b3-ca0a-4ca9-99cc-4c551229e14d'	System	05 Aug 2020 00:07:04
User entered 'No (N)'	System	05 Aug 2020 00:07:04

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:06:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c16b56b3-ca0a-4ca9-99cc-4c551229e14d'	System	05 Aug 2020 00:07:04
User entered '04 Aug 2020 19:06'	System	05 Aug 2020 00:07:04

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '04 Aug 2020 18:51'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '04 Aug 2020 21:21'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '04 Aug 2020 22:16'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 2'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:14', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '065d4653-8e01-4ccb-8246-f90acbc40867'	System	06 Aug 2020 07:38:32
User entered 'Yes (Y)'	System	06 Aug 2020 07:38:32

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:22', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '065d4653-8e01-4ccb-8246-f90acbc40867'	System	06 Aug 2020 07:38:32
User entered '97.7'	System	06 Aug 2020 07:38:32

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:05', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '065d4653-8e01-4ccb-8246-f90acbc40867'	System	06 Aug 2020 07:38:32
User entered 'No (N)'	System	06 Aug 2020 07:38:32

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:28', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '065d4653-8e01-4ccb-8246-f90acbc40867'	System	06 Aug 2020 07:38:32
User entered '06 Aug 2020 02:38'	System	06 Aug 2020 07:38:32

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 3'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:01:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6dba920b-aec4-4452-b86b-abca706d6761'	System	06 Aug 2020 17:02:12
User entered 'Yes (Y)'	System	06 Aug 2020 17:02:12

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:01', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6dba920b-aec4-4452-b86b-abca706d6761' User entered '98.3'	System	06 Aug 2020 17:02:12
	System	06 Aug 2020 17:02:12

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:04', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6dba920b-aec4-4452-b86b-abca706d6761'	System	06 Aug 2020 17:02:12
User entered 'No (N)'	System	06 Aug 2020 17:02:12

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:08', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6dba920b-aec4-4452-b86b-abca706d6761'	System	06 Aug 2020 17:02:12
User entered '06 Aug 2020 12:02'	System	06 Aug 2020 17:02:12

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 4'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:41:23', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '849f5708-a39a-4de3-ab9d-cc74bd30f0ab'	System	07 Aug 2020 23:42:00
User entered 'Yes (Y)'	System	07 Aug 2020 23:42:00

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:41:34', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '849f5708-a39a-4de3-ab9d-cc74bd30f0ab'	System	07 Aug 2020 23:42:00
User entered '97.3'	System	07 Aug 2020 23:42:00

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:41:48', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '849f5708-a39a-4de3-ab9d-cc74bd30f0ab'	System	07 Aug 2020 23:42:00
User entered 'No (N)'	System	07 Aug 2020 23:42:00

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:41:55', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '849f5708-a39a-4de3-ab9d-cc74bd30f0ab'	System	07 Aug 2020 23:42:00
User entered '07 Aug 2020 18:41'	System	07 Aug 2020 23:42:00

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 5'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:21:37', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a39de40b-6d09-4b10-b4c0-3aca48536eee'	System	09 Aug 2020 00:21:54
User entered 'Yes (Y)'	System	09 Aug 2020 00:21:54

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:21:43', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a39de40b-6d09-4b10-b4c0-3aca48536eee'	System	09 Aug 2020 00:21:54
User entered '97.8'	System	09 Aug 2020 00:21:54

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:21:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a39de40b-6d09-4b10-b4c0-3aca48536eee'	System	09 Aug 2020 00:21:54
User entered 'No (N)'	System	09 Aug 2020 00:21:54

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:21:50', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a39de40b-6d09-4b10-b4c0-3aca48536eee'	System	09 Aug 2020 00:21:54
User entered '08 Aug 2020 19:21'	System	09 Aug 2020 00:21:54

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 6'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:36:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '47e5d5ae-c562-443e-bd7c-6a26638bdf0'	System	10 Aug 2020 01:37:11
User entered 'Yes (Y)'	System	10 Aug 2020 01:37:11

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '47e5d5ae-c562-443e-bd7c-6a26638bdf0'	System	10 Aug 2020 01:37:11
User entered '97.9'	System	10 Aug 2020 01:37:11

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:03', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '47e5d5ae-c562-443e-bd7c-6a26638bdf0'	System	10 Aug 2020 01:37:11
User entered 'No (N)'	System	10 Aug 2020 01:37:11

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:05', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '47e5d5ae-c562-443e-bd7c-6a26638bdfe0'	System	10 Aug 2020 01:37:11
User entered '09 Aug 2020 20:37'	System	10 Aug 2020 01:37:11

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 7'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:17:45', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '52d37921-3910-4e9f-9bcc-4fe8ebcceb9a'	System	11 Aug 2020 02:18:03
User entered 'Yes (Y)'	System	11 Aug 2020 02:18:03

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:17:53', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '52d37921-3910-4e9f-9bcc-4fe8ebcceb9a'	System	11 Aug 2020 02:18:03
User entered '97.5'	System	11 Aug 2020 02:18:03

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:17:57', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '52d37921-3910-4e9f-9bcc-4fe8ebcceb9a'	System	11 Aug 2020 02:18:03
User entered 'No (N)'	System	11 Aug 2020 02:18:03

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '52d37921-3910-4e9f-9bcc-4fe8ebcceb9a'	System	11 Aug 2020 02:18:03
User entered '10 Aug 2020 21:18'	System	11 Aug 2020 02:18:03

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:45
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:06:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8c9b1c32-82a4-426b-961a-8becd45980d9'	System	05 Aug 2020 00:07:26
User entered 'None (1)'	System	05 Aug 2020 00:07:26

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:02', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8c9b1c32-82a4-426b-961a-8becd45980d9'	System	05 Aug 2020 00:07:26
User entered 'No (N)'	System	05 Aug 2020 00:07:26

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:05', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8c9b1c32-82a4-426b-961a-8becd45980d9'	System	05 Aug 2020 00:07:26
User entered 'No (N)'	System	05 Aug 2020 00:07:26

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:08', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8c9b1c32-82a4-426b-961a-8becd45980d9'	System	05 Aug 2020 00:07:26
User entered 'None (1)'	System	05 Aug 2020 00:07:26

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:19', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8c9b1c32-82a4-426b-961a-8becd45980d9'	System	05 Aug 2020 00:07:26
User entered '04 Aug 2020 19:07'	System	05 Aug 2020 00:07:26

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '04 Aug 2020 18:51'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '04 Aug 2020 21:21'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:45:50

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:45:50

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '04 Aug 2020 22:16'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 2'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:38', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '85522fb4-1375-4001-a11b-ae8cc681dc83'	System	06 Aug 2020 07:38:59
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 07:38:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:41', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '85522fb4-1375-4001-a11b-ae8cc681dc83'	System	06 Aug 2020 07:38:59
User entered 'No (N)'	System	06 Aug 2020 07:38:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:44', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '85522fb4-1375-4001-a11b-ae8cc681dc83'	System	06 Aug 2020 07:38:59
User entered 'No (N)'	System	06 Aug 2020 07:38:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:48', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '85522fb4-1375-4001-a11b-ae8cc681dc83'	System	06 Aug 2020 07:38:59
User entered 'None (1)'	System	06 Aug 2020 07:38:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:51', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '85522fb4-1375-4001-a11b-ae8cc681dc83'	System	06 Aug 2020 07:38:59
User entered '06 Aug 2020 02:38'	System	06 Aug 2020 07:38:59

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 3'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:12', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '55ccf40b-4edd-4adc-abf9-4bf3e153c166'	System	06 Aug 2020 17:02:24
User entered 'None (1)'	System	06 Aug 2020 17:02:24

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:14', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '55ccf40b-4edd-4adc-abf9-4bf3e153c166'	System	06 Aug 2020 17:02:24
User entered 'No (N)'	System	06 Aug 2020 17:02:24

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:16', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '55ccf40b-4edd-4adc-abf9-4bf3e153c166'	System	06 Aug 2020 17:02:24
User entered 'No (N)'	System	06 Aug 2020 17:02:24

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:18', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '55ccf40b-4edd-4adc-abf9-4bf3e153c166'	System	06 Aug 2020 17:02:24
User entered 'None (1)'	System	06 Aug 2020 17:02:24

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:20', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '55ccf40b-4edd-4adc-abf9-4bf3e153c166'	System	06 Aug 2020 17:02:24
User entered '06 Aug 2020 12:02'	System	06 Aug 2020 17:02:24

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 4'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:41:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b12af5f2-7964-46ba-9ddf-6784f869c7dd'	System	07 Aug 2020 23:42:16
User entered 'None (1)'	System	07 Aug 2020 23:42:16

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:01', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b12af5f2-7964-46ba-9ddf-6784f869c7dd'	System	07 Aug 2020 23:42:16
User entered 'No (N)'	System	07 Aug 2020 23:42:16

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:04', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b12af5f2-7964-46ba-9ddf-6784f869c7dd'	System	07 Aug 2020 23:42:16
User entered 'No (N)'	System	07 Aug 2020 23:42:16

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:08', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b12af5f2-7964-46ba-9ddf-6784f869c7dd'	System	07 Aug 2020 23:42:16
User entered 'None (1)'	System	07 Aug 2020 23:42:16

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:11', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b12af5f2-7964-46ba-9ddf-6784f869c7dd'	System	07 Aug 2020 23:42:16
User entered '07 Aug 2020 18:42'	System	07 Aug 2020 23:42:16

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 5'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:21:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2b4c713d-a3fc-44b7-9262-356420a12ff2'	System	09 Aug 2020 00:22:07
User entered 'None (1)'	System	09 Aug 2020 00:22:07

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:21:56', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2b4c713d-a3fc-44b7-9262-356420a12ff2'	System	09 Aug 2020 00:22:07
User entered 'No (N)'	System	09 Aug 2020 00:22:07

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:21:57', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2b4c713d-a3fc-44b7-9262-356420a12ff2'	System	09 Aug 2020 00:22:07
User entered 'No (N)'	System	09 Aug 2020 00:22:07

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:21:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2b4c713d-a3fc-44b7-9262-356420a12ff2'	System	09 Aug 2020 00:22:07
User entered 'None (1)'	System	09 Aug 2020 00:22:07

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:01', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2b4c713d-a3fc-44b7-9262-356420a12ff2'	System	09 Aug 2020 00:22:07
User entered '08 Aug 2020 19:22'	System	09 Aug 2020 00:22:07

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 6'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:16', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '03393355-8082-40ea-85e9-a5e1917317a4'	System	10 Aug 2020 01:37:28
User entered 'None (1)'	System	10 Aug 2020 01:37:28

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:14', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '03393355-8082-40ea-85e9-a5e1917317a4'	System	10 Aug 2020 01:37:28
User entered 'No (N)'	System	10 Aug 2020 01:37:28

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:18', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '03393355-8082-40ea-85e9-a5e1917317a4'	System	10 Aug 2020 01:37:28
User entered 'No (N)'	System	10 Aug 2020 01:37:28

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:20', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '03393355-8082-40ea-85e9-a5e1917317a4'	System	10 Aug 2020 01:37:28
User entered 'None (1)'	System	10 Aug 2020 01:37:28

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:22', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '03393355-8082-40ea-85e9-a5e1917317a4'	System	10 Aug 2020 01:37:28
User entered '09 Aug 2020 20:37'	System	10 Aug 2020 01:37:28

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 7'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:03', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '45c8c67d-7265-48bf-9725-5f32d2b834d5'	System	11 Aug 2020 02:18:13
User entered 'None (1)'	System	11 Aug 2020 02:18:13

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:05', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '45c8c67d-7265-48bf-9725-5f32d2b834d5'	System	11 Aug 2020 02:18:13
User entered 'No (N)'	System	11 Aug 2020 02:18:13

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:06', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '45c8c67d-7265-48bf-9725-5f32d2b834d5'	System	11 Aug 2020 02:18:13
User entered 'No (N)'	System	11 Aug 2020 02:18:13

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:07', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '45c8c67d-7265-48bf-9725-5f32d2b834d5'	System	11 Aug 2020 02:18:13
User entered 'None (1)'	System	11 Aug 2020 02:18:13

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:09', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '45c8c67d-7265-48bf-9725-5f32d2b834d5'	System	11 Aug 2020 02:18:13
User entered '10 Aug 2020 21:18'	System	11 Aug 2020 02:18:13

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:45:50
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:28', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7b8f2315-f460-4074-ac5e-f89c26b8ac3c'	System	05 Aug 2020 00:08:08
User entered 'No interference with activity (1)'	System	05 Aug 2020 00:08:08

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7b8f2315-f460-4074-ac5e-f89c26b8ac3c'	System	05 Aug 2020 00:08:08
User entered 'None (0)'	System	05 Aug 2020 00:08:08

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:33', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7b8f2315-f460-4074-ac5e-f89c26b8ac3c'	System	05 Aug 2020 00:08:08
User entered 'None (0)'	System	05 Aug 2020 00:08:08

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:39', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7b8f2315-f460-4074-ac5e-f89c26b8ac3c'	System	05 Aug 2020 00:08:08
User entered 'None (0)'	System	05 Aug 2020 00:08:08

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:45', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7b8f2315-f460-4074-ac5e-f89c26b8ac3c'	System	05 Aug 2020 00:08:08
User entered 'None (0)'	System	05 Aug 2020 00:08:08

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7b8f2315-f460-4074-ac5e-f89c26b8ac3c'	System	05 Aug 2020 00:08:08
User entered 'None (0)'	System	05 Aug 2020 00:08:08

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:07:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7b8f2315-f460-4074-ac5e-f89c26b8ac3c'	System	05 Aug 2020 00:08:08
User entered 'No (N)'	System	05 Aug 2020 00:08:08

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-04T19:08:02', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7b8f2315-f460-4074-ac5e-f89c26b8ac3c'	System	05 Aug 2020 00:08:08
User entered '04 Aug 2020 19:08'	System	05 Aug 2020 00:08:08

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '04 Aug 2020 18:51'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '04 Aug 2020 21:21'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:00

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '04 Aug 2020 22:16'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 2'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:38:57', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0ed6f414-2e2f-4f9e-8926-d3cb7a1bbcf2'	System	06 Aug 2020 07:39:24
User entered 'None (0)'	System	06 Aug 2020 07:39:24

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:39:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0ed6f414-2e2f-4f9e-8926-d3cb7a1bbcf2'	System	06 Aug 2020 07:39:24
User entered 'None (0)'	System	06 Aug 2020 07:39:24

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:39:03', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0ed6f414-2e2f-4f9e-8926-d3cb7a1bbcf2'	System	06 Aug 2020 07:39:24
User entered 'None (0)'	System	06 Aug 2020 07:39:24

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:39:06', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0ed6f414-2e2f-4f9e-8926-d3cb7a1bbcf2'	System	06 Aug 2020 07:39:24
User entered 'None (0)'	System	06 Aug 2020 07:39:24

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:39:09', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0ed6f414-2e2f-4f9e-8926-d3cb7a1bbcf2'	System	06 Aug 2020 07:39:24
User entered 'None (0)'	System	06 Aug 2020 07:39:24

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:39:11', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0ed6f414-2e2f-4f9e-8926-d3cb7a1bbcf2'	System	06 Aug 2020 07:39:24
User entered 'None (0)'	System	06 Aug 2020 07:39:24

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:39:15', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0ed6f414-2e2f-4f9e-8926-d3cb7a1bbcf2'	System	06 Aug 2020 07:39:24
User entered 'No (N)'	System	06 Aug 2020 07:39:24

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T02:39:18', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0ed6f414-2e2f-4f9e-8926-d3cb7a1bbcf2'	System	06 Aug 2020 07:39:24
User entered '06 Aug 2020 02:39'	System	06 Aug 2020 07:39:24

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 3'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:24', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7e412911-7d8c-4538-8660-d60ffc755f87'	System	06 Aug 2020 17:02:41
User entered 'None (0)'	System	06 Aug 2020 17:02:41

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:25', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7e412911-7d8c-4538-8660-d60ffc755f87'	System	06 Aug 2020 17:02:41
User entered 'None (0)'	System	06 Aug 2020 17:02:41

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:27', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7e412911-7d8c-4538-8660-d60ffc755f87'	System	06 Aug 2020 17:02:41
User entered 'None (0)'	System	06 Aug 2020 17:02:41

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:29', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7e412911-7d8c-4538-8660-d60ffc755f87'	System	06 Aug 2020 17:02:41
User entered 'None (0)'	System	06 Aug 2020 17:02:41

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7e412911-7d8c-4538-8660-d60ffc755f87'	System	06 Aug 2020 17:02:41
User entered 'None (0)'	System	06 Aug 2020 17:02:41

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:32', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7e412911-7d8c-4538-8660-d60ffc755f87'	System	06 Aug 2020 17:02:41
User entered 'None (0)'	System	06 Aug 2020 17:02:41

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:35', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7e412911-7d8c-4538-8660-d60ffc755f87'	System	06 Aug 2020 17:02:41
User entered 'No (N)'	System	06 Aug 2020 17:02:41

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-06T12:02:37', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7e412911-7d8c-4538-8660-d60ffc755f87'	System	06 Aug 2020 17:02:41
User entered '06 Aug 2020 12:02'	System	06 Aug 2020 17:02:41

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 4'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:17', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7acf1f33-6387-4266-ab7d-9bd2bc3585c7'	System	07 Aug 2020 23:42:43
User entered 'None (0)'	System	07 Aug 2020 23:42:43

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:19', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7acf1f33-6387-4266-ab7d-9bd2bc3585c7'	System	07 Aug 2020 23:42:43
User entered 'None (0)'	System	07 Aug 2020 23:42:43

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:22', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7acf1f33-6387-4266-ab7d-9bd2bc3585c7'	System	07 Aug 2020 23:42:43
User entered 'None (0)'	System	07 Aug 2020 23:42:43

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:26', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7acf1f33-6387-4266-ab7d-9bd2bc3585c7'	System	07 Aug 2020 23:42:43
User entered 'None (0)'	System	07 Aug 2020 23:42:43

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:28', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7acf1f33-6387-4266-ab7d-9bd2bc3585c7'	System	07 Aug 2020 23:42:43
User entered 'None (0)'	System	07 Aug 2020 23:42:43

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7acf1f33-6387-4266-ab7d-9bd2bc3585c7'	System	07 Aug 2020 23:42:43
User entered 'None (0)'	System	07 Aug 2020 23:42:43

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:36', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7acf1f33-6387-4266-ab7d-9bd2bc3585c7'	System	07 Aug 2020 23:42:43
User entered 'No (N)'	System	07 Aug 2020 23:42:43

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-07T18:42:39', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7acf1f33-6387-4266-ab7d-9bd2bc3585c7'	System	07 Aug 2020 23:42:43
User entered '07 Aug 2020 18:42'	System	07 Aug 2020 23:42:43

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 5'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:09', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '53b02692-9783-433c-9cea-a17f49dce6cf'	System	09 Aug 2020 00:22:25
User entered 'None (0)'	System	09 Aug 2020 00:22:25

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:10', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '53b02692-9783-433c-9cea-a17f49dce6cf'	System	09 Aug 2020 00:22:25
User entered 'None (0)'	System	09 Aug 2020 00:22:25

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:12', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '53b02692-9783-433c-9cea-a17f49dce6cf'	System	09 Aug 2020 00:22:25
User entered 'None (0)'	System	09 Aug 2020 00:22:25

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:13', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '53b02692-9783-433c-9cea-a17f49dce6cf'	System	09 Aug 2020 00:22:25
User entered 'None (0)'	System	09 Aug 2020 00:22:25

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:14', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '53b02692-9783-433c-9cea-a17f49dce6cf'	System	09 Aug 2020 00:22:25
User entered 'None (0)'	System	09 Aug 2020 00:22:25

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:16', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '53b02692-9783-433c-9cea-a17f49dce6cf'	System	09 Aug 2020 00:22:25
User entered 'None (0)'	System	09 Aug 2020 00:22:25

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:17', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '53b02692-9783-433c-9cea-a17f49dce6cf'	System	09 Aug 2020 00:22:25
User entered 'No (N)'	System	09 Aug 2020 00:22:25

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-08T19:22:20', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '53b02692-9783-433c-9cea-a17f49dce6cf'	System	09 Aug 2020 00:22:25
User entered '08 Aug 2020 19:22'	System	09 Aug 2020 00:22:25

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 6'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:29', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8a243070-287d-4873-a0c2-e36d71e0bd71'	System	10 Aug 2020 01:37:50
User entered 'No interference with activity (1)'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:31', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8a243070-287d-4873-a0c2-e36d71e0bd71'	System	10 Aug 2020 01:37:50
User entered 'None (0)'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:33', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8a243070-287d-4873-a0c2-e36d71e0bd71'	System	10 Aug 2020 01:37:50
User entered 'None (0)'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:37', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8a243070-287d-4873-a0c2-e36d71e0bd71'	System	10 Aug 2020 01:37:50
User entered 'None (0)'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:39', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8a243070-287d-4873-a0c2-e36d71e0bd71'	System	10 Aug 2020 01:37:50
User entered 'None (0)'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:40', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8a243070-287d-4873-a0c2-e36d71e0bd71'	System	10 Aug 2020 01:37:50
User entered 'None (0)'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:43', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8a243070-287d-4873-a0c2-e36d71e0bd71'	System	10 Aug 2020 01:37:50
User entered 'No (N)'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-09T20:37:46', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8a243070-287d-4873-a0c2-e36d71e0bd71'	System	10 Aug 2020 01:37:50
User entered '09 Aug 2020 20:37'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 7'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:13', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '926d872f-bb87-4591-98ed-35e30491ee3d'	System	11 Aug 2020 02:18:31
User entered 'None (0)'	System	11 Aug 2020 02:18:31

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:15', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '926d872f-bb87-4591-98ed-35e30491ee3d'	System	11 Aug 2020 02:18:31
User entered 'None (0)'	System	11 Aug 2020 02:18:31

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:16', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '926d872f-bb87-4591-98ed-35e30491ee3d'	System	11 Aug 2020 02:18:31
User entered 'None (0)'	System	11 Aug 2020 02:18:31

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:17', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '926d872f-bb87-4591-98ed-35e30491ee3d'	System	11 Aug 2020 02:18:31
User entered 'None (0)'	System	11 Aug 2020 02:18:31

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:18', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '926d872f-bb87-4591-98ed-35e30491ee3d'	System	11 Aug 2020 02:18:31
User entered 'None (0)'	System	11 Aug 2020 02:18:31

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:22', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '926d872f-bb87-4591-98ed-35e30491ee3d'	System	11 Aug 2020 02:18:31
User entered 'None (0)'	System	11 Aug 2020 02:18:31

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:24', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '926d872f-bb87-4591-98ed-35e30491ee3d'	System	11 Aug 2020 02:18:31
User entered 'No (N)'	System	11 Aug 2020 02:18:31

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-10T21:18:26', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '926d872f-bb87-4591-98ed-35e30491ee3d'	System	11 Aug 2020 02:18:31
User entered '10 Aug 2020 21:18'	System	11 Aug 2020 02:18:31

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:00
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:07
Data entry locked.	System	10 Aug 2020 01:37:50
User entered 'Day 8'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-11T20:01:52', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b4f18e27-2e2c-403e-92ee-0f8b04167c76'	System	12 Aug 2020 01:02:00
User entered 'No (N)'	System	12 Aug 2020 01:02:00

US3062079

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-08-11T20:01:55', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b4f18e27-2e2c-403e-92ee-0f8b04167c76'	System	12 Aug 2020 01:02:00
User entered '11 Aug 2020 20:01'	System	12 Aug 2020 01:02:00

US3062079

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:07
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 01:37:50

US3062079

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:07
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 01:37:50

US3062079

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	13 Aug 2020 18:48:52
	(b) (4)	

US3062079

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '12 Aug 2020'	Janna Martinez (b) (4)	13 Aug 2020 18:48:52

US3062079

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	13 Aug 2020 18:48:52

US3062079

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:51
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	13 Aug 2020 18:48:52
	(b) (4)	

US3062079

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	13 Aug 2020 18:48:58
	(b) (4)	

US3062079

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:47
User entered 'I'	System	13 Aug 2020 18:48:58

US3062079

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	21 Aug 2020 21:39:14
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	21 Aug 2020 21:38:57
User entered 'Yes (Y)'	Janna Martinez (b) (4)	21 Aug 2020 21:38:57
	(b) (4)	

US3062079

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '21 Aug 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	21 Aug 2020 21:39:14
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	21 Aug 2020 21:38:57
	(b) (4)	

US3062079

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	21 Aug 2020 21:38:57
	(b) (4)	

US3062079

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4)	21 Aug 2020 21:38:57
	(b) (4)	

US3062079

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:47
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	21 Aug 2020 21:38:49
	(b) (4)	

US3062079

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:45:47
User entered 'I'	System	21 Aug 2020 21:38:49

US3062079

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:45
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	27 Aug 2020 15:26:48
	(b) (4)	

US3062079

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:45
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '27 Aug 2020'	Janna Martinez (b) (4)	27 Aug 2020 15:26:48
	(b) (4)	

US3062079

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:45
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	27 Aug 2020 15:26:48
	(b) (4)	

US3062079

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:45
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	27 Aug 2020 15:26:48
	(b) (4)	

US3062079

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:45
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Yes (Y)'	(b) (4) Janna Martinez (b) (4)	27 Aug 2020 15:26:50
	(b) (4)	

US3062079

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:00:45
User entered 'I'	System	27 Aug 2020 15:26:50

US3062079

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Brianna Burton (b) (4)	04 Sep 2020 19:23:31
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '4 Sep 2020'	Brianna Burton (b) (4)	04 Sep 2020 19:23:31
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[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 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Clinic (Clinic)'	Brianna Burton (b) (4)	04 Sep 2020 19:23:31
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'VISIT2'	System	04 Sep 2020 19:23:31

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '13:24'	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered '04 Sep 2020 13:24'	System	04 Sep 2020 22:48:03

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '98.4' F	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Oral (Oral)'	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '100'	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'bpm'	System	04 Sep 2020 22:48:03

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'breaths/min'	System	04 Sep 2020 22:48:03

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '133'	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'mmHg'	System	04 Sep 2020 22:48:03

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '87'	Janna Martinez (b) (4)	04 Sep 2020 22:48:03
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'mmHg'	System	04 Sep 2020 22:48:03

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '14:50'	Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered '04 Sep 2020 14:50'	System	04 Sep 2020 22:48:35

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '98.5' F	Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered 'Oral (Oral)'	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '101'	Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'bpm'	System	04 Sep 2020 22:48:35

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '16'	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'breaths/min'	System	04 Sep 2020 22:48:35

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '135'	Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'mmHg'	System	04 Sep 2020 22:48:35

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '94'	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 22:48:35
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'mmHg'	System	04 Sep 2020 22:48:35

US3062079

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:48:59
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:48:59
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:49:39
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:49:39
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Urine (URINE)'	Janna Martinez (b) (4)	04 Sep 2020 22:49:39
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Janna Martinez (b) (4)	04 Sep 2020 22:49:39
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	04 Sep 2020 22:49:39
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	(b) (4) Janna Martinez (b) (4)	04 Sep 2020 22:49:39
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User closed query 'Per CDM: Was FSH sample collected? = No. Per CCGs page 24 only if 'Yes' is selected, the date and time of FSH collection is to be recorded in these fields. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 09:57:42
Query 'Per CDM: Was FSH sample collected? = No. Per CCGs page 24 only if 'Yes' is selected, the date and time of FSH collection is to be recorded in these fields. Please review and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	17 Sep 2020 14:32:01
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4) (b) (4)	17 Sep 2020 14:31:56
User opened query 'Per CDM: Was FSH sample collected? = No. Per CCGs page 24 only if 'Yes' is selected, the date and time of FSH collection is to be recorded in these fields. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:49:24
User entered '13:37' reason for change: Data Entry Error	Sherry Henning (b) (4) (b) (4)	16 Sep 2020 20:36:25
User entered empty.	Janna Martinez (b) (4) (b) (4)	04 Sep 2020 22:49:39

US3062079

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered empty.	System	04 Sep 2020 22:49:39

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Brianna Burton (b) (4)	04 Sep 2020 19:23:54
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Brianna Burton (b) (4)	04 Sep 2020 19:23:54
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Brianna Burton (b) (4)	04 Sep 2020 19:23:54
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 19:23:54

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '4 Sep 2020'	Brianna Burton (b) (4)	04 Sep 2020 19:23:54
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '14:19'	Brianna Burton (b) (4)	04 Sep 2020 19:23:54
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered '4 Sep 2020 14:19'	System	04 Sep 2020 19:23:54

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Brianna Burton (b) (4)	04 Sep 2020 19:23:54
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'ONCE'	System	04 Sep 2020 19:23:54

US3062079

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:59:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 19:23:54

US3062079

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:50:16
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:50:16
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '13:36'	Janna Martinez (b) (4)	04 Sep 2020 22:50:16
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered '04 Sep 2020 13:36'	System	04 Sep 2020 22:50:16

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '04 Sep 2020'	Janna Martinez (b) (4)	04 Sep 2020 22:50:30
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Janna Martinez (b) (4)	04 Sep 2020 22:50:30
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:50:30
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '13:32'	Janna Martinez (b) (4)	04 Sep 2020 22:50:30
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered '04 Sep 2020 13:32'	System	04 Sep 2020 22:50:30

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Janna Martinez (b) (4)	04 Sep 2020 22:50:30
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	04 Sep 2020 22:50:30
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered empty.	Janna Martinez (b) (4)	04 Sep 2020 22:50:30

US3062079

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered empty.	System	04 Sep 2020 22:50:30

US3062079

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	04 Sep 2020 22:46:38
	(b) (4)	

US3062079

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'I'	System	04 Sep 2020 22:46:38

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:13', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '5152594c-ac2c-41e4-96c4-2df2e7b9a541'	System	04 Sep 2020 19:54:33
User entered 'Yes (Y)'	System	04 Sep 2020 19:54:33

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:18', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '5152594c-ac2c-41e4-96c4-2df2e7b9a541'	System	04 Sep 2020 19:54:33
User entered '98.5'	System	04 Sep 2020 19:54:33

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:21', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '5152594c-ac2c-41e4-96c4-2df2e7b9a541'	System	04 Sep 2020 19:54:33
User entered 'No (N)'	System	04 Sep 2020 19:54:33

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:25', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '5152594c-ac2c-41e4-96c4-2df2e7b9a541'	System	04 Sep 2020 19:54:33
User entered '04 Sep 2020 14:54'	System	04 Sep 2020 19:54:33

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '04 Sep 2020 14:39'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '04 Sep 2020 17:09'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:24:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9f20aa67-2f21-4454-9a99-d9b7446bfb86'	System	04 Sep 2020 23:25:04
User entered 'Yes (Y)'	System	04 Sep 2020 23:25:04

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:24:52', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9f20aa67-2f21-4454-9a99-d9b7446bfb86'	System	04 Sep 2020 23:25:04
User entered '98.4'	System	04 Sep 2020 23:25:04

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:24:55', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9f20aa67-2f21-4454-9a99-d9b7446bfb86'	System	04 Sep 2020 23:25:04
User entered 'No (N)'	System	04 Sep 2020 23:25:04

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:24:58', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9f20aa67-2f21-4454-9a99-d9b7446bfb86'	System	04 Sep 2020 23:25:04
User entered '04 Sep 2020 18:24'	System	04 Sep 2020 23:25:04

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '04 Sep 2020 18:04'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 2'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:04:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'f13b8a12-6b15-436e-b7f2-f2e41de17c5f'	System	06 Sep 2020 02:05:36
User entered 'Yes (Y)'	System	06 Sep 2020 02:05:36

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:15', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'f13b8a12-6b15-436e-b7f2-f2e41de17c5f'	System	06 Sep 2020 02:05:36
User entered '96.8'	System	06 Sep 2020 02:05:36

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:19', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'f13b8a12-6b15-436e-b7f2-f2e41de17c5f'	System	06 Sep 2020 02:05:36
User entered 'Yes (Y)'	System	06 Sep 2020 02:05:36

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'to be updated at next TC' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 10:15:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:25', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'f13b8a12-6b15-436e-b7f2-f2e41de17c5f'	marissa Mueller (b) (4)	10 Sep 2020 00:25:33
User entered '1'	(b) (4)	
	System	06 Sep 2020 02:05:36
	System	06 Sep 2020 02:05:36
	System	06 Sep 2020 02:05:36

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:25', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'f13b8a12-6b15-436e-b7f2-f2e41de17c5f' User entered '0'	System	06 Sep 2020 02:05:36
	System	06 Sep 2020 02:05:36

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:29', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'f13b8a12-6b15-436e-b7f2-f2e41de17c5f'	System	06 Sep 2020 02:05:36
User entered '05 Sep 2020 21:05'	System	06 Sep 2020 02:05:36

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 3'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:53:53', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b7e9cd9b-0450-4ee5-a151-bba87a6b140c'	System	07 Sep 2020 00:54:21
User entered 'Yes (Y)'	System	07 Sep 2020 00:54:21

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:53:58', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b7e9cd9b-0450-4ee5-a151-bba87a6b140c'	System	07 Sep 2020 00:54:21
User entered '97.9'	System	07 Sep 2020 00:54:21

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:03', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b7e9cd9b-0450-4ee5-a151-bba87a6b140c'	System	07 Sep 2020 00:54:21
User entered 'Yes (Y)'	System	07 Sep 2020 00:54:21

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'to be collected at next TC' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 10:15:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	marissa Mueller (b) (4)	10 Sep 2020 00:25:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:08', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b7e9cd9b-0450-4ee5-a151-bba87a6b140c'	(b) (4)	
User entered '1'	System	07 Sep 2020 00:54:21

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:08', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b7e9cd9b-0450-4ee5-a151-bba87a6b140c'	System	07 Sep 2020 00:54:21
User entered '0'	System	07 Sep 2020 00:54:21

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:15', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b7e9cd9b-0450-4ee5-a151-bba87a6b140c'	System	07 Sep 2020 00:54:21
User entered '06 Sep 2020 19:54'	System	07 Sep 2020 00:54:21

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 4'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:52:37', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2f3edc6c-3011-4f2e-a024-ab9538d39ba5'	System	08 Sep 2020 03:54:28
User entered 'Yes (Y)'	System	08 Sep 2020 03:54:28

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:13', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2f3edc6c-3011-4f2e-a024-ab9538d39ba5'	System	08 Sep 2020 03:54:28
User entered '97.8'	System	08 Sep 2020 03:54:28

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:17', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2f3edc6c-3011-4f2e-a024-ab9538d39ba5'	System	08 Sep 2020 03:54:28
User entered 'No (N)'	System	08 Sep 2020 03:54:28

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:19', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '2f3edc6c-3011-4f2e-a024-ab9538d39ba5'	System	08 Sep 2020 03:54:28
User entered '07 Sep 2020 22:54'	System	08 Sep 2020 03:54:28

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 5'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T20:59:34', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '512938c6-e662-4082-9813-70d8748c8eb7'	System	09 Sep 2020 02:00:13
User entered 'Yes (Y)'	System	09 Sep 2020 02:00:13

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T20:59:39', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '512938c6-e662-4082-9813-70d8748c8eb7'	System	09 Sep 2020 02:00:13
User entered '97.7'	System	09 Sep 2020 02:00:13

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:02', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '512938c6-e662-4082-9813-70d8748c8eb7'	System	09 Sep 2020 02:00:13
User entered 'No (N)'	System	09 Sep 2020 02:00:13

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:04', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '512938c6-e662-4082-9813-70d8748c8eb7'	System	09 Sep 2020 02:00:13
User entered '08 Sep 2020 21:00'	System	09 Sep 2020 02:00:13

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 6'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:21:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6814080a-7da7-43ce-83b6-a9391777f18d'	System	10 Sep 2020 02:22:01
User entered 'Yes (Y)'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:21:34', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6814080a-7da7-43ce-83b6-a9391777f18d'	System	10 Sep 2020 02:22:01
User entered '97.7'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:21:43', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6814080a-7da7-43ce-83b6-a9391777f18d'	System	10 Sep 2020 02:22:01
User entered 'Yes (Y)'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'to be collected at next TC ' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 10:15:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:21:48', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6814080a-7da7-43ce-83b6-a9391777f18d'	marissa Mueller (b) (4)	11 Sep 2020 16:58:37
User entered '1'	(b) (4)	
	System	10 Sep 2020 02:22:01
	System	10 Sep 2020 02:22:01
	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:21:48', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6814080a-7da7-43ce-83b6-a9391777f18d' User entered '0'	System	10 Sep 2020 02:22:01
	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:21:52', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6814080a-7da7-43ce-83b6-a9391777f18d'	System	10 Sep 2020 02:22:01
User entered '09 Sep 2020 21:21'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 7'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:01:29', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da428a7e-14cf-4276-8421-9092b4d7a0ea'	System	11 Sep 2020 12:02:10
User entered 'Yes (Y)'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:01:34', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da428a7e-14cf-4276-8421-9092b4d7a0ea'	System	11 Sep 2020 12:02:10
User entered '98.3'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:01:48', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da428a7e-14cf-4276-8421-9092b4d7a0ea'	System	11 Sep 2020 12:02:10
User entered 'Yes (Y)'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'to be collected at next TC ' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 10:15:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:01:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da428a7e-14cf-4276-8421-9092b4d7a0ea'	marissa Mueller (b) (4)	11 Sep 2020 16:58:51
User entered '1'	(b) (4)	
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	11 Sep 2020 12:02:10
User entered '1'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:01:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da428a7e-14cf-4276-8421-9092b4d7a0ea' User entered '0'	System	11 Sep 2020 12:02:10
	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:01:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da428a7e-14cf-4276-8421-9092b4d7a0ea'	System	11 Sep 2020 12:02:10
User entered '11 Sep 2020 07:01'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	10 Sep 2020 02:22:01
User entered 'Day 8'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T20:14:40', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8263f67f-599f-4cac-8cf9-05f9397320dd'	System	12 Sep 2020 01:15:05
User entered 'Yes (Y)'	System	12 Sep 2020 01:15:05

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T20:14:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8263f67f-599f-4cac-8cf9-05f9397320dd'	System	12 Sep 2020 01:15:05
User entered '98.4'	System	12 Sep 2020 01:15:05

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T20:14:53', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8263f67f-599f-4cac-8cf9-05f9397320dd'	System	12 Sep 2020 01:15:05
User entered 'Yes (Y)'	System	12 Sep 2020 01:15:05

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'to be collected at next TC' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 10:15:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T20:14:56', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8263f67f-599f-4cac-8cf9-05f9397320dd'	marissa Mueller (b) (4)	14 Sep 2020 13:37:53
User entered '1'	(b) (4)	
	System	12 Sep 2020 01:15:05
	System	12 Sep 2020 01:15:05
	System	12 Sep 2020 01:15:05

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T20:14:56', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8263f67f-599f-4cac-8cf9-05f9397320dd'	System	12 Sep 2020 01:15:05
User entered '0'	System	12 Sep 2020 01:15:05

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T20:14:58', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '8263f67f-599f-4cac-8cf9-05f9397320dd'	System	12 Sep 2020 01:15:05
User entered '11 Sep 2020 20:14'	System	12 Sep 2020 01:15:05

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
Data entry locked.	System	11 Sep 2020 12:02:10
User entered 'Day 9'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-12T21:29:56', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c06bd9b0-5b6b-4d65-be81-54ee3ec93203'	System	13 Sep 2020 02:30:11
User entered 'Yes (Y)'	System	13 Sep 2020 02:30:11

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-12T21:30:01', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c06bd9b0-5b6b-4d65-be81-54ee3ec93203'	System	13 Sep 2020 02:30:11
User entered '97.8'	System	13 Sep 2020 02:30:11

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-12T21:30:03', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c06bd9b0-5b6b-4d65-be81-54ee3ec93203'	System	13 Sep 2020 02:30:11
User entered 'No (N)'	System	13 Sep 2020 02:30:11

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-12T21:30:06', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c06bd9b0-5b6b-4d65-be81-54ee3ec93203'	System	13 Sep 2020 02:30:11
User entered '12 Sep 2020 21:30'	System	13 Sep 2020 02:30:11

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:14
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:28', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '78dae2ed-dfc1-4e1d-b438-1ca784161112'	System	04 Sep 2020 19:54:42
User entered 'None (1)'	System	04 Sep 2020 19:54:42

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '78dae2ed-dfc1-4e1d-b438-1ca784161112'	System	04 Sep 2020 19:54:42
User entered 'No (N)'	System	04 Sep 2020 19:54:42

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:32', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '78dae2ed-dfc1-4e1d-b438-1ca784161112'	System	04 Sep 2020 19:54:42
User entered 'No (N)'	System	04 Sep 2020 19:54:42

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:35', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '78dae2ed-dfc1-4e1d-b438-1ca784161112'	System	04 Sep 2020 19:54:42
User entered 'None (1)'	System	04 Sep 2020 19:54:42

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:38', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '78dae2ed-dfc1-4e1d-b438-1ca784161112'	System	04 Sep 2020 19:54:42
User entered '04 Sep 2020 14:54'	System	04 Sep 2020 19:54:42

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '04 Sep 2020 14:39'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '04 Sep 2020 17:09'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:25', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b555375c-2782-4d80-87ec-492e553f99b0'	System	04 Sep 2020 23:25:39
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 23:25:39

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:28', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b555375c-2782-4d80-87ec-492e553f99b0'	System	04 Sep 2020 23:25:39
User entered 'No (N)'	System	04 Sep 2020 23:25:39

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:31', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b555375c-2782-4d80-87ec-492e553f99b0'	System	04 Sep 2020 23:25:39
User entered 'No (N)'	System	04 Sep 2020 23:25:39

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:33', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b555375c-2782-4d80-87ec-492e553f99b0'	System	04 Sep 2020 23:25:39
User entered 'None (1)'	System	04 Sep 2020 23:25:39

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:35', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'b555375c-2782-4d80-87ec-492e553f99b0'	System	04 Sep 2020 23:25:39
User entered '04 Sep 2020 18:25'	System	04 Sep 2020 23:25:39

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '04 Sep 2020 18:04'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 2'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:37', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'cb769d93-5450-4193-bd1a-6560dd7db783'	System	06 Sep 2020 02:06:05
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 02:06:05

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:40', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'cb769d93-5450-4193-bd1a-6560dd7db783'	System	06 Sep 2020 02:06:05
User entered 'No (N)'	System	06 Sep 2020 02:06:05

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'cb769d93-5450-4193-bd1a-6560dd7db783'	System	06 Sep 2020 02:06:05
User entered 'No (N)'	System	06 Sep 2020 02:06:05

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:49', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'cb769d93-5450-4193-bd1a-6560dd7db783'	System	06 Sep 2020 02:06:05
User entered 'None (1)'	System	06 Sep 2020 02:06:05

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:05:58', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'cb769d93-5450-4193-bd1a-6560dd7db783'	System	06 Sep 2020 02:06:05
User entered '05 Sep 2020 21:05'	System	06 Sep 2020 02:06:05

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 3'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:24', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e0fb726d-94d3-4dcb-a1f8-9f80504c65f7'	System	07 Sep 2020 00:54:45
User entered 'None (1)'	System	07 Sep 2020 00:54:45

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:27', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e0fb726d-94d3-4dcb-a1f8-9f80504c65f7'	System	07 Sep 2020 00:54:45
User entered 'No (N)'	System	07 Sep 2020 00:54:45

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e0fb726d-94d3-4dcb-a1f8-9f80504c65f7'	System	07 Sep 2020 00:54:45
User entered 'No (N)'	System	07 Sep 2020 00:54:45

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:36', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e0fb726d-94d3-4dcb-a1f8-9f80504c65f7'	System	07 Sep 2020 00:54:45
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 00:54:45

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:39', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e0fb726d-94d3-4dcb-a1f8-9f80504c65f7'	System	07 Sep 2020 00:54:45
User entered '06 Sep 2020 19:54'	System	07 Sep 2020 00:54:45

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 4'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:23', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '635c6172-c5fd-4c13-b5c4-08258017c49b'	System	08 Sep 2020 03:54:46
User entered 'None (1)'	System	08 Sep 2020 03:54:46

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:26', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '635c6172-c5fd-4c13-b5c4-08258017c49b'	System	08 Sep 2020 03:54:46
User entered 'No (N)'	System	08 Sep 2020 03:54:46

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:28', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '635c6172-c5fd-4c13-b5c4-08258017c49b'	System	08 Sep 2020 03:54:46
User entered 'No (N)'	System	08 Sep 2020 03:54:46

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '635c6172-c5fd-4c13-b5c4-08258017c49b'	System	08 Sep 2020 03:54:46
User entered 'None (1)'	System	08 Sep 2020 03:54:46

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:36', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '635c6172-c5fd-4c13-b5c4-08258017c49b'	System	08 Sep 2020 03:54:46
User entered '07 Sep 2020 22:54'	System	08 Sep 2020 03:54:46

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 5'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:09', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ce72d779-35f5-4421-bc61-caa21881855c'	System	09 Sep 2020 02:00:24
User entered 'None (1)'	System	09 Sep 2020 02:00:24

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:11', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ce72d779-35f5-4421-bc61-caa21881855c'	System	09 Sep 2020 02:00:24
User entered 'No (N)'	System	09 Sep 2020 02:00:24

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:12', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ce72d779-35f5-4421-bc61-caa21881855c'	System	09 Sep 2020 02:00:24
User entered 'No (N)'	System	09 Sep 2020 02:00:24

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:15', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ce72d779-35f5-4421-bc61-caa21881855c'	System	09 Sep 2020 02:00:24
User entered 'None (1)'	System	09 Sep 2020 02:00:24

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:18', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ce72d779-35f5-4421-bc61-caa21881855c'	System	09 Sep 2020 02:00:24
User entered '08 Sep 2020 21:00'	System	09 Sep 2020 02:00:24

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 6'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:21:56', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e4c3e6f0-d1e3-4a9a-826e-5a8a3d9b829b'	System	10 Sep 2020 02:22:15
User entered 'None (1)'	System	10 Sep 2020 02:22:15

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:21:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e4c3e6f0-d1e3-4a9a-826e-5a8a3d9b829b'	System	10 Sep 2020 02:22:15
User entered 'No (N)'	System	10 Sep 2020 02:22:15

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e4c3e6f0-d1e3-4a9a-826e-5a8a3d9b829b'	System	10 Sep 2020 02:22:15
User entered 'No (N)'	System	10 Sep 2020 02:22:15

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:02', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e4c3e6f0-d1e3-4a9a-826e-5a8a3d9b829b'	System	10 Sep 2020 02:22:15
User entered 'None (1)'	System	10 Sep 2020 02:22:15

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:08', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e4c3e6f0-d1e3-4a9a-826e-5a8a3d9b829b'	System	10 Sep 2020 02:22:15
User entered '09 Sep 2020 21:22'	System	10 Sep 2020 02:22:15

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 7'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:05', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0cc2771c-c902-4bd0-b730-eadb6f7a0546'	System	11 Sep 2020 12:02:26
User entered 'None (1)'	System	11 Sep 2020 12:02:26

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:07', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0cc2771c-c902-4bd0-b730-eadb6f7a0546'	System	11 Sep 2020 12:02:26
User entered 'No (N)'	System	11 Sep 2020 12:02:26

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:08', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0cc2771c-c902-4bd0-b730-eadb6f7a0546'	System	11 Sep 2020 12:02:26
User entered 'No (N)'	System	11 Sep 2020 12:02:26

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:10', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0cc2771c-c902-4bd0-b730-eadb6f7a0546'	System	11 Sep 2020 12:02:26
User entered 'None (1)'	System	11 Sep 2020 12:02:26

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:19', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '0cc2771c-c902-4bd0-b730-eadb6f7a0546'	System	11 Sep 2020 12:02:26
User entered '11 Sep 2020 07:02'	System	11 Sep 2020 12:02:26

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:19
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:41', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9ae0b8a7-20e7-43b5-bd2c-c7c7ea360f63'	System	04 Sep 2020 19:55:02
User entered 'None (0)'	System	04 Sep 2020 19:55:02

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:43', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9ae0b8a7-20e7-43b5-bd2c-c7c7ea360f63'	System	04 Sep 2020 19:55:02
User entered 'None (0)'	System	04 Sep 2020 19:55:02

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:44', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9ae0b8a7-20e7-43b5-bd2c-c7c7ea360f63'	System	04 Sep 2020 19:55:02
User entered 'None (0)'	System	04 Sep 2020 19:55:02

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:46', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9ae0b8a7-20e7-43b5-bd2c-c7c7ea360f63'	System	04 Sep 2020 19:55:02
User entered 'None (0)'	System	04 Sep 2020 19:55:02

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9ae0b8a7-20e7-43b5-bd2c-c7c7ea360f63'	System	04 Sep 2020 19:55:02
User entered 'None (0)'	System	04 Sep 2020 19:55:02

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:49', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9ae0b8a7-20e7-43b5-bd2c-c7c7ea360f63'	System	04 Sep 2020 19:55:02
User entered 'None (0)'	System	04 Sep 2020 19:55:02

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:53', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9ae0b8a7-20e7-43b5-bd2c-c7c7ea360f63'	System	04 Sep 2020 19:55:02
User entered 'No (N)'	System	04 Sep 2020 19:55:02

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T14:54:55', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9ae0b8a7-20e7-43b5-bd2c-c7c7ea360f63'	System	04 Sep 2020 19:55:02
User entered '04 Sep 2020 14:54'	System	04 Sep 2020 19:55:02

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '04 Sep 2020 14:39'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '04 Sep 2020 17:09'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:43', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd9b80198-d7b6-47e9-819d-c022126d4d5f'	System	04 Sep 2020 23:26:09
User entered 'None (0)'	System	04 Sep 2020 23:26:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:45', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd9b80198-d7b6-47e9-819d-c022126d4d5f'	System	04 Sep 2020 23:26:09
User entered 'None (0)'	System	04 Sep 2020 23:26:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:46', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd9b80198-d7b6-47e9-819d-c022126d4d5f'	System	04 Sep 2020 23:26:09
User entered 'None (0)'	System	04 Sep 2020 23:26:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd9b80198-d7b6-47e9-819d-c022126d4d5f'	System	04 Sep 2020 23:26:09
User entered 'None (0)'	System	04 Sep 2020 23:26:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:49', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd9b80198-d7b6-47e9-819d-c022126d4d5f' User entered 'None (0)'	System	04 Sep 2020 23:26:09
	System	04 Sep 2020 23:26:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:53', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd9b80198-d7b6-47e9-819d-c022126d4d5f'	System	04 Sep 2020 23:26:09
User entered 'None (0)'	System	04 Sep 2020 23:26:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:25:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd9b80198-d7b6-47e9-819d-c022126d4d5f'	System	04 Sep 2020 23:26:09
User entered 'No (N)'	System	04 Sep 2020 23:26:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-04T18:26:05', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd9b80198-d7b6-47e9-819d-c022126d4d5f'	System	04 Sep 2020 23:26:09
User entered '04 Sep 2020 18:26'	System	04 Sep 2020 23:26:09

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '04 Sep 2020 18:04'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 2'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:06:26', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '71853085-07c8-4602-911e-c5e167aeab87'	System	06 Sep 2020 02:07:01
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 02:07:01

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:06:29', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '71853085-07c8-4602-911e-c5e167aeab87'	System	06 Sep 2020 02:07:01
User entered 'None (0)'	System	06 Sep 2020 02:07:01

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:06:31', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '71853085-07c8-4602-911e-c5e167aeab87'	System	06 Sep 2020 02:07:01
User entered 'None (0)'	System	06 Sep 2020 02:07:01

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:06:33', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '71853085-07c8-4602-911e-c5e167aeab87'	System	06 Sep 2020 02:07:01
User entered 'None (0)'	System	06 Sep 2020 02:07:01

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:06:38', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '71853085-07c8-4602-911e-c5e167aeab87'	System	06 Sep 2020 02:07:01
User entered 'None (0)'	System	06 Sep 2020 02:07:01

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:06:41', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '71853085-07c8-4602-911e-c5e167aeab87'	System	06 Sep 2020 02:07:01
User entered 'None (0)'	System	06 Sep 2020 02:07:01

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:06:45', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '71853085-07c8-4602-911e-c5e167aeab87'	System	06 Sep 2020 02:07:01
User entered 'No (N)'	System	06 Sep 2020 02:07:01

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-05T21:06:56', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '71853085-07c8-4602-911e-c5e167aeab87'	System	06 Sep 2020 02:07:01
User entered '05 Sep 2020 21:06'	System	06 Sep 2020 02:07:01

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 3'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:45', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9410f6af-2732-4bd7-aafd-f8e11b25f055'	System	07 Sep 2020 00:55:13
User entered 'No interference with activity (1)'	System	07 Sep 2020 00:55:13

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:50', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9410f6af-2732-4bd7-aafd-f8e11b25f055'	System	07 Sep 2020 00:55:13
User entered 'None (0)'	System	07 Sep 2020 00:55:13

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:52', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9410f6af-2732-4bd7-aafd-f8e11b25f055'	System	07 Sep 2020 00:55:13
User entered 'None (0)'	System	07 Sep 2020 00:55:13

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:53', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9410f6af-2732-4bd7-aafd-f8e11b25f055'	System	07 Sep 2020 00:55:13
User entered 'None (0)'	System	07 Sep 2020 00:55:13

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:54:55', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9410f6af-2732-4bd7-aafd-f8e11b25f055'	System	07 Sep 2020 00:55:13
User entered 'None (0)'	System	07 Sep 2020 00:55:13

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:55:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9410f6af-2732-4bd7-aafd-f8e11b25f055'	System	07 Sep 2020 00:55:13
User entered 'None (0)'	System	07 Sep 2020 00:55:13

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:55:03', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9410f6af-2732-4bd7-aafd-f8e11b25f055'	System	07 Sep 2020 00:55:13
User entered 'No (N)'	System	07 Sep 2020 00:55:13

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-06T19:55:09', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9410f6af-2732-4bd7-aafd-f8e11b25f055'	System	07 Sep 2020 00:55:13
User entered '06 Sep 2020 19:55'	System	07 Sep 2020 00:55:13

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 4'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:40', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '86b19d7d-1956-4a91-bd6c-66e68e0a18ad'	System	08 Sep 2020 03:55:17
User entered 'None (0)'	System	08 Sep 2020 03:55:17

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:42', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '86b19d7d-1956-4a91-bd6c-66e68e0a18ad'	System	08 Sep 2020 03:55:17
User entered 'None (0)'	System	08 Sep 2020 03:55:17

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:44', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '86b19d7d-1956-4a91-bd6c-66e68e0a18ad'	System	08 Sep 2020 03:55:17
User entered 'None (0)'	System	08 Sep 2020 03:55:17

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:46', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '86b19d7d-1956-4a91-bd6c-66e68e0a18ad'	System	08 Sep 2020 03:55:17
User entered 'None (0)'	System	08 Sep 2020 03:55:17

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:54:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '86b19d7d-1956-4a91-bd6c-66e68e0a18ad'	System	08 Sep 2020 03:55:17
User entered 'None (0)'	System	08 Sep 2020 03:55:17

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:55:02', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '86b19d7d-1956-4a91-bd6c-66e68e0a18ad'	System	08 Sep 2020 03:55:17
User entered 'None (0)'	System	08 Sep 2020 03:55:17

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:55:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '86b19d7d-1956-4a91-bd6c-66e68e0a18ad'	System	08 Sep 2020 03:55:17
User entered 'Yes (Y)'	System	08 Sep 2020 03:55:17

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-07T22:55:10', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '86b19d7d-1956-4a91-bd6c-66e68e0a18ad'	System	08 Sep 2020 03:55:17
User entered '07 Sep 2020 22:55'	System	08 Sep 2020 03:55:17

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 5'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:26', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '84be916b-d5ce-4173-90bd-09143ced590a'	System	09 Sep 2020 02:00:52
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		09 Sep 2020 02:00:52

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:28', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '84be916b-d5ce-4173-90bd-09143ced590a'	System	09 Sep 2020 02:00:52
User entered 'None (0)'	System	09 Sep 2020 02:00:52

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '84be916b-d5ce-4173-90bd-09143ced590a'	System	09 Sep 2020 02:00:52
User entered 'None (0)'	System	09 Sep 2020 02:00:52

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:31', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '84be916b-d5ce-4173-90bd-09143ced590a'	System	09 Sep 2020 02:00:52
User entered 'None (0)'	System	09 Sep 2020 02:00:52

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:34', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '84be916b-d5ce-4173-90bd-09143ced590a'	System	09 Sep 2020 02:00:52
User entered 'None (0)'	System	09 Sep 2020 02:00:52

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:36', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '84be916b-d5ce-4173-90bd-09143ced590a'	System	09 Sep 2020 02:00:52
User entered 'None (0)'	System	09 Sep 2020 02:00:52

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:43', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '84be916b-d5ce-4173-90bd-09143ced590a'	System	09 Sep 2020 02:00:52
User entered 'Yes (Y)'	System	09 Sep 2020 02:00:52

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-08T21:00:46', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '84be916b-d5ce-4173-90bd-09143ced590a'	System	09 Sep 2020 02:00:52
User entered '08 Sep 2020 21:00'	System	09 Sep 2020 02:00:52

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 6'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:12', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e2f8dda7-0e78-459f-bb8a-8d026c78b19a'	System	10 Sep 2020 02:22:33
User entered 'None (0)'	System	10 Sep 2020 02:22:33

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:14', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e2f8dda7-0e78-459f-bb8a-8d026c78b19a'	System	10 Sep 2020 02:22:33
User entered 'None (0)'	System	10 Sep 2020 02:22:33

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:15', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e2f8dda7-0e78-459f-bb8a-8d026c78b19a'	System	10 Sep 2020 02:22:33
User entered 'None (0)'	System	10 Sep 2020 02:22:33

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:16', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e2f8dda7-0e78-459f-bb8a-8d026c78b19a'	System	10 Sep 2020 02:22:33
User entered 'None (0)'	System	10 Sep 2020 02:22:33

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:18', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e2f8dda7-0e78-459f-bb8a-8d026c78b19a'	System	10 Sep 2020 02:22:33
User entered 'None (0)'	System	10 Sep 2020 02:22:33

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:20', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e2f8dda7-0e78-459f-bb8a-8d026c78b19a'	System	10 Sep 2020 02:22:33
User entered 'None (0)'	System	10 Sep 2020 02:22:33

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:23', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e2f8dda7-0e78-459f-bb8a-8d026c78b19a'	System	10 Sep 2020 02:22:33
User entered 'Yes (Y)'	System	10 Sep 2020 02:22:33

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-09T21:22:26', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e2f8dda7-0e78-459f-bb8a-8d026c78b19a'	System	10 Sep 2020 02:22:33
User entered '09 Sep 2020 21:22'	System	10 Sep 2020 02:22:33

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
Data entry locked.	System	04 Sep 2020 19:23:54
User entered 'Day 7'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:23', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6425069b-3126-41f6-bdb5-e6d55f0ae66e'	System	11 Sep 2020 12:02:45
User entered 'None (0)'	System	11 Sep 2020 12:02:45

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:25', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6425069b-3126-41f6-bdb5-e6d55f0ae66e'	System	11 Sep 2020 12:02:45
User entered 'None (0)'	System	11 Sep 2020 12:02:45

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:27', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6425069b-3126-41f6-bdb5-e6d55f0ae66e'	System	11 Sep 2020 12:02:45
User entered 'None (0)'	System	11 Sep 2020 12:02:45

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:29', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6425069b-3126-41f6-bdb5-e6d55f0ae66e'	System	11 Sep 2020 12:02:45
User entered 'None (0)'	System	11 Sep 2020 12:02:45

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:31', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6425069b-3126-41f6-bdb5-e6d55f0ae66e'	System	11 Sep 2020 12:02:45
User entered 'None (0)'	System	11 Sep 2020 12:02:45

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:32', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6425069b-3126-41f6-bdb5-e6d55f0ae66e'	System	11 Sep 2020 12:02:45
User entered 'None (0)'	System	11 Sep 2020 12:02:45

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:35', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6425069b-3126-41f6-bdb5-e6d55f0ae66e'	System	11 Sep 2020 12:02:45
User entered 'Yes (Y)'	System	11 Sep 2020 12:02:45

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T07:02:38', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '6425069b-3126-41f6-bdb5-e6d55f0ae66e'	System	11 Sep 2020 12:02:45
User entered '11 Sep 2020 07:02'	System	11 Sep 2020 12:02:45

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:24
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:23:54

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:29
Data entry locked.	System	10 Sep 2020 02:22:01
User entered 'Day 8'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T20:15:11', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9140c823-5463-41bb-b937-80dcfda23830'	System	12 Sep 2020 01:15:18
User entered 'No (N)'	System	12 Sep 2020 01:15:18

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-11T20:15:13', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9140c823-5463-41bb-b937-80dcfda23830'	System	12 Sep 2020 01:15:18
User entered '11 Sep 2020 20:15'	System	12 Sep 2020 01:15:18

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:29
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:29
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 02:22:01

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:29
Data entry locked.	System	11 Sep 2020 12:02:10
User entered 'Day 9'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:59:21

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)	03 Apr 2021 16:46:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-12T21:30:10', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'f4963647-1cc0-4e2c-9561-babcb32868aa'	System	13 Sep 2020 02:30:18
User entered 'No (N)'	System	13 Sep 2020 02:30:18

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-09-12T21:30:12', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'f4963647-1cc0-4e2c-9561-babcb32868aa'	System	13 Sep 2020 02:30:18
User entered '12 Sep 2020 21:30'	System	13 Sep 2020 02:30:18

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:29
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 12:02:10

US3062079

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 14:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:29
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 12:02:10

US3062079

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	16 Sep 2020 20:28:54
	(b) (4)	

US3062079

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '11 Sep 2020'	Sherry Henning (b) (4)	16 Sep 2020 20:28:54
	(b) (4)	

US3062079

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	16 Sep 2020 20:28:54
	(b) (4)	

US3062079

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	16 Sep 2020 20:28:54
	(b) (4)	

US3062079

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	16 Sep 2020 20:28:44
	(b) (4)	

US3062079

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	16 Sep 2020 20:28:44

US3062079

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	25 Sep 2020 15:36:38
	(b) (4)	

US3062079

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '18 Sep 2020'	Janna Martinez (b) (4)	25 Sep 2020 15:36:38
	(b) (4)	

US3062079

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	25 Sep 2020 15:36:38
	(b) (4)	

US3062079

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	25 Sep 2020 15:36:38
	(b) (4)	

US3062079

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	25 Sep 2020 15:36:59
	(b) (4)	

US3062079

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	25 Sep 2020 15:36:59

US3062079

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	25 Sep 2020 15:37:20
	(b) (4)	

US3062079

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '25 Sep 2020'	Janna Martinez (b) (4)	25 Sep 2020 15:37:20
	(b) (4)	

US3062079

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	25 Sep 2020 15:37:20
	(b) (4)	

US3062079

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	25 Sep 2020 15:37:20
	(b) (4)	

US3062079

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	25 Sep 2020 15:37:25
	(b) (4)	

US3062079

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	25 Sep 2020 15:37:25

US3062079

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Sep 2020 20:33:27
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '30 Sep 2020'	Janna Martinez (b) (4)	30 Sep 2020 20:33:27
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Clinic (Clinic)'	Janna Martinez (b) (4)	30 Sep 2020 20:33:27
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'VISIT3'	System	30 Sep 2020 20:33:27

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '30 Sep 2020'	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '14:17'	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '30 Sep 2020 14:17'	System	30 Sep 2020 20:33:56

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '98.3' F	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '92'	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'bpm'	System	30 Sep 2020 20:33:56

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'breaths/min'	System	30 Sep 2020 20:33:56

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
User entered '135'	(b) (4) Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'mmHg'	System	30 Sep 2020 20:33:56

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '89'	Janna Martinez (b) (4)	30 Sep 2020 20:33:56
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'mmHg'	System	30 Sep 2020 20:33:56

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03

US3062079

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03

US3062079

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	30 Sep 2020 20:33:59
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:33:59
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Sep 2020 20:34:14
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '30 Sep 2020'	Janna Martinez (b) (4)	30 Sep 2020 20:34:14
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered '14:27'	Janna Martinez (b) (4)	30 Sep 2020 20:34:14
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered '30 Sep 2020 14:27'	System	30 Sep 2020 20:34:14

US3062079

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:22:29
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Sep 2020 20:35:49
	(b) (4)	

US3062079

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	30 Sep 2020 20:35:49

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 64'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-05T19:59:02', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c1781610-de14-4d25-9e8f-e2e9e404e05c'	System	06 Oct 2020 00:59:17
User entered 'No (N)'	System	06 Oct 2020 00:59:17

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-05T19:59:07', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c1781610-de14-4d25-9e8f-e2e9e404e05c'	System	06 Oct 2020 00:59:17
User entered 'No (N)'	System	06 Oct 2020 00:59:17

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-05T19:59:12', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'c1781610-de14-4d25-9e8f-e2e9e404e05c'	System	06 Oct 2020 00:59:17
User entered '05 Oct 2020 19:59:12'	System	06 Oct 2020 00:59:17

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 71'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-11T05:31:17', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'eee6417a-7fce-4eef-adc3-e18613bb69e9'	System	11 Oct 2020 10:31:33
User entered 'No (N)'	System	11 Oct 2020 10:31:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-11T05:31:21', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'eee6417a-7fce-4eef-adc3-e18613bb69e9'	System	11 Oct 2020 10:31:33
User entered 'No (N)'	System	11 Oct 2020 10:31:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-11T05:31:24', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'eee6417a-7fce-4eef-adc3-e18613bb69e9'	System	11 Oct 2020 10:31:33
User entered '11 Oct 2020 05:31:24'	System	11 Oct 2020 10:31:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 78'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-22T18:22:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e27dc3f3-71a9-4906-978e-ff0cda06239f'	System	22 Oct 2020 23:23:11
User entered 'No (N)'	System	22 Oct 2020 23:23:11

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-22T18:23:04', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e27dc3f3-71a9-4906-978e-ff0cda06239f'	System	22 Oct 2020 23:23:11
User entered 'No (N)'	System	22 Oct 2020 23:23:11

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-10-22T18:23:07', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e27dc3f3-71a9-4906-978e-ff0cda06239f' User entered '22 Oct 2020 18:23:07'	System	22 Oct 2020 23:23:11
	System	22 Oct 2020 23:23:11

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 92'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-01T05:02:52', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '97118e29-ce3b-4413-a33f-53c80fd758ae'	System	01 Nov 2020 11:03:10
User entered 'No (N)'	System	01 Nov 2020 11:03:10

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-01T05:02:56', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '97118e29-ce3b-4413-a33f-53c80fd758ae'	System	01 Nov 2020 11:03:10
User entered 'No (N)'	System	01 Nov 2020 11:03:10

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-01T05:03:02', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '97118e29-ce3b-4413-a33f-53c80fd758ae'	System	01 Nov 2020 11:03:10
User entered '01 Nov 2020 05:03:02'	System	01 Nov 2020 11:03:10

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 99'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-11T14:59:05', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9f7e8bfd-1e0a-4130-bcfc-121c423f10f6'	System	11 Nov 2020 20:59:24
User entered 'No (N)'	System	11 Nov 2020 20:59:24

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-11T14:59:08', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9f7e8bfd-1e0a-4130-bcfc-121c423f10f6'	System	11 Nov 2020 20:59:24
User entered 'No (N)'	System	11 Nov 2020 20:59:24

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-11T14:59:17', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9f7e8bfd-1e0a-4130-bcfc-121c423f10f6'	System	11 Nov 2020 20:59:24
User entered '11 Nov 2020 14:59:17'	System	11 Nov 2020 20:59:24

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered 'Day 106'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-18T14:31:34', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd4f4716d-7646-465b-91d8-acd6a562581f'	System	18 Nov 2020 20:32:03
User entered 'No (N)'	System	18 Nov 2020 20:32:03

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-18T14:31:52', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd4f4716d-7646-465b-91d8-acd6a562581f'	System	18 Nov 2020 20:32:03
User entered 'No (N)'	System	18 Nov 2020 20:32:03

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-18T14:31:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd4f4716d-7646-465b-91d8-acd6a562581f'	System	18 Nov 2020 20:32:03
User entered '18 Nov 2020 14:31:54'	System	18 Nov 2020 20:32:03

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 23:44:33

US3062079

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:46:40
Data entry locked.	System	04 Aug 2020 23:44:33
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 23:44:33

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (519ee5185261c392)', Time: '2020-11-26T20:48:37', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9a347030-b321-484e-b233-9c10f12164dd'	System	27 Nov 2020 02:48:55
User entered 'No (N)'	System	27 Nov 2020 02:48:55

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Have you been exposed to someone with 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 (519ee5185261c392)', Time: '2020-11-26T20:48:39', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9a347030-b321-484e-b233-9c10f12164dd'	System	27 Nov 2020 02:48:55
User entered 'No (N)'	System	27 Nov 2020 02:48:55

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-11-26T20:48:51', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9a347030-b321-484e-b233-9c10f12164dd'	System	27 Nov 2020 02:48:55
User entered '26 Nov 2020 20:48:51'	System	27 Nov 2020 02:48:55

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (519ee5185261c392)', Time: '2020-12-03T06:18:48', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e74b8884-935d-4749-a5b4-ee9406a48032'	System	03 Dec 2020 12:19:07
User entered 'No (N)'	System	03 Dec 2020 12:19:07

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (519ee5185261c392)', Time: '2020-12-03T06:18:56', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e74b8884-935d-4749-a5b4-ee9406a48032'	System	03 Dec 2020 12:19:07
User entered 'No (N)'	System	03 Dec 2020 12:19:07

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-12-03T06:19:01', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'e74b8884-935d-4749-a5b4-ee9406a48032'	System	03 Dec 2020 12:19:07
User entered '03 Dec 2020 06:19:01'	System	03 Dec 2020 12:19:07

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (519ee5185261c392)', Time: '2020-12-14T16:49:49', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7061739d-d65f-41a6-a5c3-49e5e4afb29b'	System	14 Dec 2020 22:50:02
User entered 'No (N)'	System	14 Dec 2020 22:50:02

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Have you been exposed to someone with 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 (519ee5185261c392)', Time: '2020-12-14T16:49:52', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7061739d-d65f-41a6-a5c3-49e5e4afb29b'	System	14 Dec 2020 22:50:02
User entered 'No (N)'	System	14 Dec 2020 22:50:02

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-12-14T16:49:55', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7061739d-d65f-41a6-a5c3-49e5e4afb29b'	System	14 Dec 2020 22:50:02
User entered '14 Dec 2020 16:49:55'	System	14 Dec 2020 22:50:02

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (519ee5185261c392)', Time: '2020-12-28T17:33:48', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a0d29926-0820-455c-9d7a-627a136d672c'	System	28 Dec 2020 23:34:05
User entered 'No (N)'	System	28 Dec 2020 23:34:05

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Have you been exposed to someone with 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 (519ee5185261c392)', Time: '2020-12-28T17:33:51', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a0d29926-0820-455c-9d7a-627a136d672c'	System	28 Dec 2020 23:34:05
User entered 'No (N)'	System	28 Dec 2020 23:34:05

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2020-12-28T17:33:54', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a0d29926-0820-455c-9d7a-627a136d672c'	System	28 Dec 2020 23:34:05
User entered '28 Dec 2020 17:33:54'	System	28 Dec 2020 23:34:05

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (519ee5185261c392)', Time: '2021-01-08T05:49:40', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9d191296-b621-4e7b-a519-ca08062e8b0a'	System	08 Jan 2021 11:50:07
User entered 'No (N)'	System	08 Jan 2021 11:50:07

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (519ee5185261c392)', Time: '2021-01-08T05:49:43', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9d191296-b621-4e7b-a519-ca08062e8b0a'	System	08 Jan 2021 11:50:07
User entered 'Yes (Y)'	System	08 Jan 2021 11:50:07

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2021-01-08T05:49:47', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9d191296-b621-4e7b-a519-ca08062e8b0a'	System	08 Jan 2021 11:50:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 11:50:07

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2021-01-08T05:49:55', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '9d191296-b621-4e7b-a519-ca08062e8b0a'	System	08 Jan 2021 11:50:07
User entered '08 Jan 2021 05:49:55'	System	08 Jan 2021 11:50:07

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (519ee5185261c392)', Time: '2021-01-18T20:47:23', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '67f36748-8d15-4299-b9fc-410b1a0bc007'	System	19 Jan 2021 02:47:39
User entered 'No (N)'	System	19 Jan 2021 02:47:39

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (519ee5185261c392)', Time: '2021-01-18T20:47:30', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '67f36748-8d15-4299-b9fc-410b1a0bc007'	System	19 Jan 2021 02:47:39
User entered 'No (N)'	System	19 Jan 2021 02:47:39

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2021-01-18T20:47:35', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '67f36748-8d15-4299-b9fc-410b1a0bc007'	System	19 Jan 2021 02:47:39
User entered '18 Jan 2021 20:47:35'	System	19 Jan 2021 02:47:39

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (519ee5185261c392)', Time: '2021-01-25T20:06:34', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a048c575-0389-4c72-be8c-82ac5ec9310f'	System	26 Jan 2021 02:07:44
User entered 'No (N)'	System	26 Jan 2021 02:07:44

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Have you been exposed to someone with 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 (519ee5185261c392)', Time: '2021-01-25T20:06:39', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a048c575-0389-4c72-be8c-82ac5ec9310f'	System	26 Jan 2021 02:07:44
User entered 'No (N)'	System	26 Jan 2021 02:07:44

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (519ee5185261c392)', Time: '2021-01-25T20:06:43', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'a048c575-0389-4c72-be8c-82ac5ec9310f' User entered '25 Jan 2021 20:06:43'	System	26 Jan 2021 02:07:44

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-01-28T04:12:16', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '089a6656-c752-49e5-b49f-94f0061ba3a8'	System	28 Jan 2021 10:12:22
User entered 'No (N)'	System	28 Jan 2021 10:12:22

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-01-28T04:12:20', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '089a6656-c752-49e5-b49f-94f0061ba3a8'	System	28 Jan 2021 10:12:22
User entered 'No (N)'	System	28 Jan 2021 10:12:22

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-01-28T04:12:25', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '089a6656-c752-49e5-b49f-94f0061ba3a8' User entered '28 Jan 2021 04:12:25'	System	28 Jan 2021 10:12:22
	System	28 Jan 2021 10:12:22

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-02-04T06:44:59', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '49bc1995-f49b-459d-b078-beb228778590'	System	04 Feb 2021 12:45:09
User entered 'No (N)'	System	04 Feb 2021 12:45:09

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-02-04T06:45:02', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '49bc1995-f49b-459d-b078-beb228778590'	System	04 Feb 2021 12:45:09
User entered 'No (N)'	System	04 Feb 2021 12:45:09

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-02-04T06:45:05', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '49bc1995-f49b-459d-b078-beb228778590'	System	04 Feb 2021 12:45:09
User entered '04 Feb 2021 06:45:05'	System	04 Feb 2021 12:45:09

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-02-12T08:08:18', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7639e2ef-20c8-4698-a334-5af23ac6099a'	System	12 Feb 2021 14:08:26
User entered 'No (N)'	System	12 Feb 2021 14:08:26

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-02-12T08:08:20', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7639e2ef-20c8-4698-a334-5af23ac6099a'	System	12 Feb 2021 14:08:26
User entered 'No (N)'	System	12 Feb 2021 14:08:26

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-02-12T08:08:24', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '7639e2ef-20c8-4698-a334-5af23ac6099a'	System	12 Feb 2021 14:08:26
User entered '12 Feb 2021 08:08:24'	System	12 Feb 2021 14:08:26

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-02-18T09:02:22', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd3f584b3-71d7-42a5-9985-ea5404462682'	System	18 Feb 2021 15:02:37
User entered 'No (N)'	System	18 Feb 2021 15:02:37

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-02-18T09:02:28', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd3f584b3-71d7-42a5-9985-ea5404462682'	System	18 Feb 2021 15:02:37
User entered 'No (N)'	System	18 Feb 2021 15:02:37

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-02-18T09:02:32', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'd3f584b3-71d7-42a5-9985-ea5404462682' User entered '18 Feb 2021 09:02:32'	System	18 Feb 2021 15:02:37
	System	18 Feb 2021 15:02:37

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-02-25T10:10:09-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da3828bb-cc89-4cf3-9131-9584654df0fd' User entered 'No (N)'	System	26 Feb 2021 03:24:59
	System	26 Feb 2021 03:24:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-02-25T10:10:11-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da3828bb-cc89-4cf3-9131-9584654df0fd' User entered 'No (N)'	System	26 Feb 2021 03:24:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-02-25T10:10:14-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'da3828bb-cc89-4cf3-9131-9584654df0fd' User entered '25 Feb 2021 10:10:14'	System	26 Feb 2021 03:24:59

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-03-05T16:30:23-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '1ae980da-e2dd-4707-a570-a9df5e78d206'	System	05 Mar 2021 22:30:30
User entered 'No (N)'	System	05 Mar 2021 22:30:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-03-05T16:30:26-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '1ae980da-e2dd-4707-a570-a9df5e78d206'	System	05 Mar 2021 22:30:30
User entered 'No (N)'	System	05 Mar 2021 22:30:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-03-05T16:30:29-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '1ae980da-e2dd-4707-a570-a9df5e78d206'	System	05 Mar 2021 22:30:30
User entered '05 Mar 2021 16:30:29'	System	05 Mar 2021 22:30:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-03-11T09:01:38-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '901f606b-47c3-4be0-9c9e-f9bbedc1abel1'	System	11 Mar 2021 15:01:52
User entered 'No (N)'	System	11 Mar 2021 15:01:52

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-03-11T09:01:42-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '901f606b-47c3-4be0-9c9e-f9bbedc1abel1'	System	11 Mar 2021 15:01:52
User entered 'No (N)'	System	11 Mar 2021 15:01:52

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-03-11T09:01:50-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '901f606b-47c3-4be0-9c9e-f9bbedc1abel'	System	11 Mar 2021 15:01:52
User entered '11 Mar 2021 09:01:50'	System	11 Mar 2021 15:01:52

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-03-19T16:39:01-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ea679b18-0d11-41e3-a5b4-c1f66ba44ace'	System	19 Mar 2021 21:39:08
User entered 'No (N)'	System	19 Mar 2021 21:39:08

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-03-19T16:39:04-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ea679b18-0d11-41e3-a5b4-c1f66ba44ace'	System	19 Mar 2021 21:39:08
User entered 'No (N)'	System	19 Mar 2021 21:39:08

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-03-19T16:39:08-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ea679b18-0d11-41e3-a5b4-c1f66ba44ace' User entered '19 Mar 2021 16:39:08'	System	19 Mar 2021 21:39:08
	System	19 Mar 2021 21:39:08

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-03-29T16:55:08-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ca127514-e946-4723-89ee-288442870d32'	System	29 Mar 2021 21:55:53
User entered 'No (N)'	System	29 Mar 2021 21:55:53

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-03-29T16:55:44-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ca127514-e946-4723-89ee-288442870d32'	System	29 Mar 2021 21:55:53
User entered 'No (N)'	System	29 Mar 2021 21:55:53

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-03-29T16:55:49-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'ca127514-e946-4723-89ee-288442870d32'	System	29 Mar 2021 21:55:53
User entered '29 Mar 2021 16:55:49'	System	29 Mar 2021 21:55:53

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-04-02T13:40:35-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '11111246-4b95-4722-80f9-f3545b687305'	System	02 Apr 2021 18:40:44
User entered 'No (N)'	System	02 Apr 2021 18:40:44

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-04-02T13:40:38-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '11111246-4b95-4722-80f9-f3545b687305'	System	02 Apr 2021 18:40:44
User entered 'No (N)'	System	02 Apr 2021 18:40:44

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-04-02T13:40:41-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '11111246-4b95-4722-80f9-f3545b687305'	System	02 Apr 2021 18:40:44
User entered '02 Apr 2021 13:40:41'	System	02 Apr 2021 18:40:44

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-04-08T07:36:07-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'acbf057-2b73-4a89-97c1-b7ad35f7dbb9'	System	08 Apr 2021 12:36:11
User entered 'No (N)'	System	08 Apr 2021 12:36:11

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-04-08T07:36:10-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'acbf057-2b73-4a89-97c1-b7ad35f7dbb9'	System	08 Apr 2021 12:36:11
User entered 'No (N)'	System	08 Apr 2021 12:36:11

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-04-08T07:36:12-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'acbf057-2b73-4a89-97c1-b7ad35f7dbb9'	System	08 Apr 2021 12:36:11
User entered '08 Apr 2021 07:36:12'	System	08 Apr 2021 12:36:11

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-04-19T11:22:43-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '39a494d2-761f-48a5-9e23-73fd2ba34417'	System	19 Apr 2021 16:22:51
User entered 'No (N)'	System	19 Apr 2021 16:22:51

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-04-19T11:22:44-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '39a494d2-761f-48a5-9e23-73fd2ba34417'	System	19 Apr 2021 16:22:51
User entered 'No (N)'	System	19 Apr 2021 16:22:51

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-04-19T11:22:47-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '39a494d2-761f-48a5-9e23-73fd2ba34417'	System	19 Apr 2021 16:22:51
User entered '19 Apr 2021 11:22:47'	System	19 Apr 2021 16:22:51

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-04-23T10:35:40-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'edf19ac6-176a-4849-aa14-b8e9685d6e91'	System	23 Apr 2021 15:36:30
User entered 'Yes (Y)'	System	23 Apr 2021 15:36:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-04-23T10:35:45-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'edf19ac6-176a-4849-aa14-b8e9685d6e91'	System	23 Apr 2021 15:36:30
User entered 'No (N)'	System	23 Apr 2021 15:36:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-04-23T10:35:50-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'edf19ac6-176a-4849-aa14-b8e9685d6e91' User entered 'No (N)'	System	23 Apr 2021 15:36:30
	System	23 Apr 2021 15:36:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-04-23T10:35:58-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'edf19ac6-176a-4849-aa14-b8e9685d6e91'	System	23 Apr 2021 15:36:30
User entered 'Yes (Y)'	System	23 Apr 2021 15:36:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-04-23T10:36:10-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'edf19ac6-176a-4849-aa14-b8e9685d6e91'	System	23 Apr 2021 15:36:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Apr 2021 15:36:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-04-23T10:36:19-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: 'edf19ac6-176a-4849-aa14-b8e9685d6e91'	System	23 Apr 2021 15:36:30
User entered '23 Apr 2021 10:36:19'	System	23 Apr 2021 15:36:30

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[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 (2eba7543bc4378f2)', Time: '2021-05-03T10:03:49-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '03d31206-b533-44d9-aa5a-8f8b45ac79b8'	System	03 May 2021 15:03:54
User entered 'No (N)'	System	03 May 2021 15:03:54

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

Have you been exposed to someone with 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 (2eba7543bc4378f2)', Time: '2021-05-03T10:03:51-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '03d31206-b533-44d9-aa5a-8f8b45ac79b8'	System	03 May 2021 15:03:54
User entered 'No (N)'	System	03 May 2021 15:03:54

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-05-03T10:03:54-05:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '03d31206-b533-44d9-aa5a-8f8b45ac79b8'	System	03 May 2021 15:03:54
User entered '03 May 2021 10:03:54'	System	03 May 2021 15:03:54

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:59:31

US3062079

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:59:31
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:59:31

US3062079

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:59:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:52:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-03-05T16:29:59-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '845c78aa-9b90-4277-9d7f-0f54b19bfb9e'	System	05 Mar 2021 22:30:17
User entered 'No (N)'	System	05 Mar 2021 22:30:17

US3062079

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:59:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:52:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2eba7543bc4378f2)', Time: '2021-03-05T16:30:14-06:00', User OID: 'PatientReportedOutcome (US3062079)', ODM File OID: '845c78aa-9b90-4277-9d7f-0f54b19bfb9e' User entered '05 Mar 2021 16:30:14'	System	05 Mar 2021 22:30:17
	System	05 Mar 2021 22:30:17

US3062079

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:29
	(b) (4)	
User entered 'Yes (Y)'	Justin Phillips (b) (4)	27 Oct 2020 20:33:04
	(b) (4)	

US3062079

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:29
	(b) (4)	
User entered '27 Oct 2020'	Justin Phillips (b) (4)	27 Oct 2020 20:33:04
	(b) (4)	

US3062079

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:29
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Justin Phillips (b) (4)	27 Oct 2020 20:33:04
	(b) (4)	

US3062079

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:29
	(b) (4)	
User entered empty.	Justin Phillips (b) (4)	27 Oct 2020 20:33:04
	(b) (4)	

US3062079

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:29
	(b) (4)	
User entered 'Yes (Y)'	Justin Phillips (b) (4)	27 Oct 2020 20:33:11
	(b) (4)	

US3062079

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:13:03
User entered 'I'	System	27 Oct 2020 20:33:11

US3062079

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	30 Nov 2020 22:56:46
	(b) (4)	

US3062079

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '30 Nov 2020'	Riley King (b) (4)	30 Nov 2020 22:56:46

US3062079

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Riley King (b) (4)	30 Nov 2020 22:56:46
	(b) (4)	

US3062079

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered empty.	Riley King (b) (4)	30 Nov 2020 22:56:46
	(b) (4)	

US3062079

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	30 Nov 2020 22:56:50

US3062079

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'I'	System	30 Nov 2020 22:56:50

US3062079

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	05 Jan 2021 23:09:02
	(b) (4)	

US3062079

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '4 Jan 2021'	Riley King (b) (4)	05 Jan 2021 23:09:02

US3062079

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Riley King (b) (4) (b) (4)	05 Jan 2021 23:09:02

US3062079

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered empty.	(b) (4) Riley King (b) (4)	05 Jan 2021 23:09:02

US3062079

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4)	05 Jan 2021 23:09:05

US3062079

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'I'	System	05 Jan 2021 23:09:05

US3062079

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	02 Feb 2021 20:09:31

US3062079

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:23:36
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'updated EDC' (Site from DM).	Colton King (b) (4) (b) (4)	04 Feb 2021 18:57:39
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	04 Feb 2021 05:00:33
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 26JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 03:58:54
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered' (Site from System).	Colton King (b) (4) (b) (4)	03 Feb 2021 21:45:45
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	02 Feb 2021 20:09:31

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US3062079

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
User entered '26 Jan 2021'	Riley King (b) (4) (b) (4)	02 Feb 2021 20:09:31

US3062079

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Riley King (b) (4) (b) (4)	02 Feb 2021 20:09:31

US3062079

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered empty.	(b) (4) Riley King (b) (4)	02 Feb 2021 20:09:31

US3062079

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 18:52:39

US3062079

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'I'	System	04 Feb 2021 18:52:39

US3062079

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	Sherry Henning (b) (4)	22 Mar 2021 16:08:23

US3062079

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '10 Mar 2021'	(b) (4) Sherry Henning (b) (4)	22 Mar 2021 16:08:23

US3062079

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Clinic (Clinic)'	(b) (4) Sherry Henning (b) (4)	22 Mar 2021 16:08:23

US3062079

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'VISIT4'	System	22 Mar 2021 16:08:23

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '10 Mar 2021'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '10:10'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered '10 Mar 2021 10:10'	System	01 Apr 2021 17:52:18

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '97.9' F	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Oral (Oral)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '77'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'bpm'	System	01 Apr 2021 17:52:18

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '14'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'breaths/min'	System	01 Apr 2021 17:52:18

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '101'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'mmHg'	System	01 Apr 2021 17:52:18

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '72'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:18
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'mmHg'	System	01 Apr 2021 17:52:18

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56

US3062079

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:59:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56

US3062079

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	22 Mar 2021 16:09:00
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:59:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered empty.	(b) (4) Sherry Henning (b) (4)	22 Mar 2021 16:09:00

US3062079

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	22 Mar 2021 16:09:15
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered '10 Mar 2021'	Sherry Henning (b) (4)	22 Mar 2021 16:09:15
	(b) (4)	

US3062079

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '10:15'	Sherry Henning (b) (4)	22 Mar 2021 16:09:15

US3062079

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered '10 Mar 2021 10:15'	System	22 Mar 2021 16:09:15

US3062079

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	Sherry Henning (b) (4)	22 Mar 2021 16:09:20

US3062079

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:56
User entered 'I'	System	22 Mar 2021 16:09:20

US3062079

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:34
	(b) (4)	

US3062079

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '31 Mar 2021'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:34
	(b) (4)	

US3062079

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:34
	(b) (4)	

US3062079

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:34
	(b) (4)	

US3062079

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 17:52:38
	(b) (4)	

US3062079

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:11
User entered '1'	System	01 Apr 2021 17:52:38

US3062079

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 18:53:22

US3062079

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	04 Feb 2021 18:53:22
	(b) (4)	

US3062079

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[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 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Clinic (Clinic)'	Colton King (b) (4)	04 Feb 2021 18:53:22

US3062079

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

Form: Visit Date

Generated On: 09 Jun 2021 14:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 18:53:22

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '26 Jan 2021'	(b) (4) Colton King (b) (4) (b) (4)	04 Feb 2021 18:54:10

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[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 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:21:37

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 18:54:10

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:21:37

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '26 Jan 2021'	Colton King (b) (4)	04 Feb 2021 18:54:10

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'mRNA-1273 (mRNA-1273)'	Colton King (b) (4)	04 Feb 2021 18:54:10

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Colton King (b) (4)	04 Feb 2021 18:54:10
	(b) (4)	

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'mRNA-1273 (mRNA-1273)'	Colton King (b) (4)	04 Feb 2021 18:54:10

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'No (N)'	Colton King (b) (4)	04 Feb 2021 18:54:10

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered empty.	System	04 Feb 2021 18:54:10

US3062079

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

Form: Unblinding

Generated On: 09 Jun 2021 14:59:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered empty.	System	04 Feb 2021 18:54:10

US3062079

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 18:54:32

US3062079

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '26 Jan 2021'	Colton King (b) (4)	04 Feb 2021 18:54:32

US3062079

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '16:35'	Colton King (b) (4)	04 Feb 2021 18:54:32

US3062079

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered '26 Jan 2021 16:35'	System	04 Feb 2021 18:54:32

US3062079

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Yes (Y)'	Colton King (b) (4)	04 Feb 2021 18:54:47

US3062079

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	04 Feb 2021 18:54:47
	(b) (4)	

US3062079

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '16:37'	Colton King (b) (4)	04 Feb 2021 18:54:47

US3062079

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:02:25
User entered '26 Jan 2021 16:37'	System	04 Feb 2021 18:54:47

US3062079

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:59:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:38
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:55:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:54
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Riley King (b) (4)	11 Sep 2020 23:28:21
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Sep 2020 20:02:47
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:14:56
User entered	System	12 Sep 2020 21:14:44
'USA-US090-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 21:14:44

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of NEPHROLITHIASIS, RECURRENT. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:13:30
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis recurrent - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 23:42:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 23:42:30
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 20:45:20
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of NEPHROLITHIASIS, RECURRENT. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jeri King (b) (4)	20 Oct 2020 20:44:44
DataPoint Un-verified.	Jeri King (b) (4)	20 Oct 2020 20:44:31
Coding entries removed.	Jeri King (b) (4)	20 Oct 2020 20:44:31
User entered 'Worsening of NEPHROLITHIASIS recurrent' reason for change: Data Entry Error	Jeri King (b) (4)	20 Oct 2020 20:44:31
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of NEPHROLITHIASIS, RECURRENT. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:35:27
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and update AE term to reflect involves the Left, Right or Bilateral KIDNEYS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:57:41
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 20:25:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	24 Sep 2020 20:25:34
Query 'Per DM CLR: Please review and update AE term to reflect involves the Left, Right or Bilateral KIDNEYS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'updated ' (Site from DM).	marissa Mueller (b) (4)	24 Sep 2020 20:24:59
Data point term sent to Coder	System	24 Sep 2020 20:24:57
Coding entries removed.	marissa Mueller (b) (4)	24 Sep 2020 20:24:54
	(b) (4)	
User entered 'Bilateral NEPHROLITHIASIS' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 20:24:54
	(b) (4)	
User opened query 'Per DM CLR: Please review and update AE term to reflect involves the Left, Right or Bilateral KIDNEYS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:29:13
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 23:34:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	11 Sep 2020 23:34:44
Data point term sent to Coder	System	11 Sep 2020 23:33:53
User entered 'Nephrolithiasis'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Yes (Y)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '07 Sep 2020'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 23:33:15

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '10 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 20:25:28
	(b) (4)	
User entered '09 Sep 2020'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 23:33:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 20:56:37
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Yes (Y)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'I'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '07 Sep 2020'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '10 Sep 2020'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:35:26
User closed query 'Per CDM: Per CCGs, when the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 09:12:45
Query 'Per CDM: Per CCGs, when the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' answered with 'updated' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 21:00:19
DataPoint Un-verified.	Jeri King (b) (4)	14 Oct 2020 21:00:11
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jeri King (b) (4)	14 Oct 2020 21:00:11
User opened query 'Per CDM: Per CCGs, when the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:06:02
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'None (NONE)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		25 Sep 2020 09:02:10
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	24 Sep 2020 20:25:37
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:29:22
User entered 'I'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Treatment Required = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).		25 Sep 2020 09:00:14
Query 'Per DM CLR: Treatment Required = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	marissa Mueller (b) (4)	24 Sep 2020 20:26:00
answered with 'updated' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Treatment Required = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:29:28
User entered 'I'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	Riley King (b) (4)	11 Sep 2020 23:33:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 14:52:35
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Faxed' (Site from Safety).	Riley King (b) (4)	03 Mar 2021 16:02:49
	(b) (4)	
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:33:05
Query 'PV Query: Since the subject was hospitalized for the event of ureteral stones, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 18:32:26
User opened query 'PV Query: Since the subject was hospitalized for the event of ureteral stones, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 14:41:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = HAD A HISTORY OF SMALL BOWEL OBSTRUCTION AS A TEENAGER, CT OF ABDOMEN AND PELVIS WITH CONTRAST DURING VISIT TO EMERGENCY ROOM and RIGHT RENAL STENT WAS ALSO PLACED AT TIME. . However, these information were not recorded in the appropriate eCRF pages (i.e., MH and ConProc). Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:26:28
Query 'Per DM CLR: SAE Narrative = HAD A HISTORY OF SMALL BOWEL OBSTRUCTION AS A TEENAGER, CT OF ABDOMEN AND PELVIS WITH CONTRAST DURING VISIT TO EMERGENCY ROOM and RIGHT RENAL STENT WAS ALSO PLACED AT TIME. . However, these information were not recorded in the appropriate eCRF pages (i.e., MH and ConProc). Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'Information has been updated' (Site from DM).	Jeri King (b) (4)	20 Oct 2020 20:58:33
User opened query 'Per DM CLR: SAE Narrative = HAD A HISTORY OF SMALL BOWEL OBSTRUCTION AS A TEENAGER, CT OF ABDOMEN AND PELVIS WITH CONTRAST DURING VISIT TO EMERGENCY ROOM and RIGHT RENAL STENT WAS ALSO PLACED AT TIME. . However, these information were not recorded in the appropriate eCRF pages (i.e., MH and ConProc). Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:35:53
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:45:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:45:07
User closed query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:45:01
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 12:44:57
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' answered with 'no test during hospital admission per records' (Site from Safety).	marissa Mueller (b) (4)	24 Sep 2020 21:44:23
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' answered with 'see narrative' (Site from Safety).	marissa Mueller (b) (4)	24 Sep 2020 20:32:04
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.' answered with 'updated' (Site from Safety).	marissa Mueller (b) (4)	24 Sep 2020 20:29:34
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? Please leave query open until information is available.' answered with 'see narrative' (Site from Safety).	marissa Mueller (b) (4)	24 Sep 2020 20:29:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject presented to Emergency Room 9/7/2020 for abdominal pain. Subject reported history of recurrent nephrolithiasis. She also reported that she had a history of small bowel obstruction as a teenager. Subject underwent CT of abdomen and pelvis with contrast during visit to emergency room. The CT showed bilateral nephrolithiasis with a partially obstructing 8mm right ureteropelvic junction stone. Subject was admitted to the hospital for pain control on 9/7/2020 and surgery was planned for 9/9/2020. On 9/9/2020, subject underwent a Cystoscopy and right ureteroscopy with laser lithotripsy. A right renal stent was also placed at time.'	marissa Mueller (b) (4)	24 Sep 2020 20:29:00
reason for change: New Information	(b) (4)	
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 01:07:58
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 01:07:58
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 01:07:32
User closed query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).	(b) (4), (b) (6)	24 Sep 2020 01:07:32
' (Site from Safety).		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 01:07:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
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)	24 Sep 2020 01:07:19
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 01:07:04
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 01:07:04
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).	marissa Mueller (b) (4)	22 Sep 2020 00:19:13
' answered with 'to be updated upon receipt of records' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'to be updated upon receipt of records' (Site from Safety).	marissa Mueller (b) (4)	22 Sep 2020 00:19:09
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' answered with 'to be updated upon receipt of records' (Site from Safety).	marissa Mueller (b) (4)	22 Sep 2020 00:19:06
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'to be updated upon receipt of records' (Site from Safety).	marissa Mueller (b) (4)	22 Sep 2020 00:19:03
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).	(b) (4), (b) (6)	21 Sep 2020 15:56:24

' (Site from Safety).

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:56:08
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:55:58
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 15:55:44
User entered 'Subject notified site today of recent hospitalization for laser removal of kidney stones and placement of a stent procedure took place on September ninth. Subject went to emergency department on September seventh and got released on September tenth. Subject was discharged with prescription for Norco 5/325 as needed for pain. Subject was discharged in stable condition with no incident. Medical records requested for further information.'	Riley King (b) (4)	11 Sep 2020 23:33:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 23:33:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 23:33:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 23:33:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	08 Oct 2020 17:07:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:44:39
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	(b) (4)	25 Sep 2020 05:44:39
Data point term sent to Coder	System	24 Sep 2020 20:56:48
User entered 'post op pain'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	08 Oct 2020 17:07:05
User entered '09 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User entered empty.	System	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)' reason for change: New Information	Sherry Henning (b) (4) (b) (4)	08 Oct 2020 14:49:32
User entered 'Yes (Y)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '16 Sep 2020' reason for change: New Information	Sherry Henning (b) (4)	08 Oct 2020 14:49:32
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User entered empty.	System	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	24 Sep 2020 20:56:14
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:44:14
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 09:13:08
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' answered with 'updated' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 21:01:11
DataPoint Un-verified.	Jeri King (b) (4)	14 Oct 2020 21:01:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jeri King (b) (4)	14 Oct 2020 21:01:00
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:06:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'None (NONE)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'l'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sherry Henning (b) (4) (b) (4)	08 Oct 2020 14:49:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:56:14

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Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User entered '0'	System	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06
User entered '1'	System	24 Sep 2020 20:56:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:06

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Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10

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Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	08 Oct 2020 17:07:05
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Urinary tract lithiasis (excl renal), PT: Ureterolithiasis, LLT: Ureterolithiasis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:40:45
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:40:45
Data point term sent to Coder	System	24 Sep 2020 20:58:51
User entered 'right obstructing ureteral stone'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User entered empty.	System	24 Sep 2020 20:57:53

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '09 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User entered empty.	System	24 Sep 2020 20:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:57:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 20:57:57
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:57
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:57:53
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:46:06
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:28:03
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'corrected' (Site from DM).	Jeri King (b) (4)	20 Oct 2020 20:47:54
DataPoint Un-verified.	Jeri King (b) (4)	20 Oct 2020 20:47:40
User entered '0' reason for change: Data Entry Error	Jeri King (b) (4)	20 Oct 2020 20:47:40
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:36:46
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '1'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User closed query 'Per DM CLR: Please verify if ConProc should be added as Action taken as there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 20:27:51
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:08:56
Query 'Per DM CLR: Please verify if ConProc should be added as Action taken as there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'corrected' (Site from DM).	Jeri King (b) (4)	20 Oct 2020 20:47:58
DataPoint Un-verified.	Jeri King (b) (4)	20 Oct 2020 20:47:40
User entered '1' reason for change: Data Entry Error	Jeri King (b) (4)	20 Oct 2020 20:47:40
User opened query 'Per DM CLR: Please verify if ConProc should be added as Action taken as there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 09:36:39
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:57:53

US3062079

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:57:53
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User entered '0'	System	24 Sep 2020 20:57:57

US3062079

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10
User entered '1'	System	24 Sep 2020 20:57:53

US3062079

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:10

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal obstructive disorders, PT: Hydronephrosis, LLT: Hydronephrosis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:40:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:40:46
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 21:00:58
User entered 'right hydronephrosis'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:00:10

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:14:46
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'ongoing as no documentation of resolvment' (Site from DM).	marissa Mueller (b) (4)	09 Dec 2020 22:24:24
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 21:06:30
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 21:06:30
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 21:00:10
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:00:10

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'I'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	marissa Mueller (b) (4)	24 Sep 2020 21:06:30
Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:00:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Sep 2020 21:00:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 21:00:10

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Transaminases increased, LLT: Transaminitis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:29:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	25 Sep 2020 05:29:45
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 21:09:05
User entered 'transminitis'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:08:39

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 21:08:39

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Related (NOT RELATED)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Not Applicable (NOT APPLICABLE)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'I'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:07:05
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 21:08:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Sep 2020 21:08:39

US3062079

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 21:08:39

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'USA-US090-2021-mRNA-1273-P301000007'	System	28 Jan 2021 19:02:44
User entered 'New'	(b) (4), (b) (6)	28 Jan 2021 19:02:44

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis recurrent - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:26:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:26:00
	(b) (4)	
User closed query 'PV Query: The subject has a history of recurrent nephrolithiasis. Was the SAE considered a worsening of the subject's medical history of recurrent nephrolithiasis? If so, please consider updating the event term in the eCRF.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:27:14
Query 'PV Query: The subject has a history of recurrent nephrolithiasis. Was the SAE considered a worsening of the subject's medical history of recurrent nephrolithiasis? If so, please consider updating the event term in the eCRF.' answered with 'reconciled ' (Site from Safety).	Riley King (b) (4)	10 Feb 2021 17:21:45
	(b) (4)	
Data point term sent to Coder	System	10 Feb 2021 17:21:17
Coding entries removed.	Riley King (b) (4)	10 Feb 2021 17:21:06
	(b) (4)	
User entered 'Worsening of recurrent nephrolithiasis' reason for change: Per Query Resolution	Riley King (b) (4)	10 Feb 2021 17:21:06
	(b) (4)	
User opened query 'PV Query: The subject has a history of recurrent nephrolithiasis. Was the SAE considered a worsening of the subject's medical history of recurrent nephrolithiasis? If so, please consider updating the event term in the eCRF.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:40:50
User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Urinary tract lithiasis (excl renal), PT: Ureterolithiasis, LLT: Ureteral calculus - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 15:45:19
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 15:45:19
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 20:25:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Ureteral stones'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:25:39

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'Yes (Y)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'No (N)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'No (N)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '3 Nov 2020'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered empty.	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 20:25:39

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'No (N)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:45:16
User closed query 'please verify as 11Dec2020 per AE log' (Site from CRA).		05 Apr 2021 20:44:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
Query 'please verify as 11Dec2020 per AE log' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	01 Apr 2021 18:53:23
	(b) (4)	
User entered '11 Dec 2020' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 18:53:02
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:41
DataPoint Verified.		29 Mar 2021 17:32:23
User opened query 'please verify as 11Dec2020 per AE log' (Site from CRA).		29 Mar 2021 16:32:57
DataPoint Un-verified.		29 Mar 2021 16:32:16
DataPoint Verified.		29 Mar 2021 16:29:33
DataPoint Un-verified.	Riley King (b) (4)	22 Mar 2021 21:56:54
	(b) (4)	
User entered '4 Nov 2020' reason for change: Data Entry Error	Riley King (b) (4)	22 Mar 2021 21:56:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '11 Dec 2020'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered empty.	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 20:25:39

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

Severity

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 18:58:55
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	08 Apr 2021 15:47:27
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	08 Apr 2021 15:47:27
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 15:47:27
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
	(b) (4), (b) (6)	
User closed query 'PV Query: Since the subject was hospitalized for the event of ureteral stones, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' (Site from Safety).		
Query 'PV Query: Since the subject was hospitalized for the event of ureteral stones, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' answered with 'updated' (Site from Safety).	Colton King (b) (4)	01 Mar 2021 21:45:08
	(b) (4)	
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Colton King (b) (4)	01 Mar 2021 21:41:13
	(b) (4)	
User opened query 'PV Query: Since the subject was hospitalized for the event of ureteral stones, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 13:03:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 18:58:55
	(b) (4)	
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	08 Apr 2021 15:47:27
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	08 Apr 2021 15:47:27
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'Yes (Y)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '0'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '0'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 10:08:21
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	marissa Mueller (b) (4)	08 Apr 2021 18:59:18
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	08 Apr 2021 18:58:55
User entered '1' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 18:58:55
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
User entered '0' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '1'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User closed query 'PV Query: Per medical records (operative note), states subject would be discharged home on 03 Nov 2020; additionally, admission order states "type admit=outpatient/same day"; as such, please review dates of hospitalization and confirm if subject was hospitalized overnight. If not, please reassess the reported seriousness criteria of hospitalization and determine if any other seriousness criteria were met (i.e.medically significant). ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:18:47
User entered '10 Dec 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 18:58:55
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
Query 'PV Query: Per medical records (operative note), states subject would be discharged home on 03 Nov 2020; additionally, admission order states "type admit=outpatient/same day"; as such, please review dates of hospitalization and confirm if subject was hospitalized overnight. If not, please reassess the reported seriousness criteria of hospitalization and determine if any other seriousness criteria were met (i.e.medically significant). ' answered with 'updated. Confirmed with hospital that this was outpatient' (Site from Safety).	marissa Mueller (b) (4)	08 Apr 2021 15:18:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Per medical records (operative note), states subject would be discharged home on 03 Nov 2020; additionally, admission order states "type admit=outpatient/same day"; as such, please review dates of hospitalization and confirm if subject was hospitalized overnight. If not, please reassess the reported seriousness criteria of hospitalization and determine if any other seriousness criteria were met (i.e.medically significant). ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:21:43
	(b) (4), (b) (6)	05 Apr 2021 20:46:06
User closed query 'please verify as 3Nov2020 per hosp record' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	05 Apr 2021 20:45:40
	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User closed query 'PV Query: Please confirm the date of hospital admission (02 Nov 2020) which is not in accordance with the medical records,03 Nov 2020. Please update EDC accordingly.' (Site from Safety). Query 'PV Query: Please confirm the date of hospital admission (02 Nov 2020) which is not in accordance with the medical records,03 Nov 2020. Please update EDC accordingly.' answered with 'reconciled ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:51:29
	Riley King (b) (4)	01 Apr 2021 18:54:41
	(b) (4)	
Query 'please verify as 3Nov2020 per hosp record' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	01 Apr 2021 18:53:53
User entered '3 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Riley King (b) (4)	01 Apr 2021 18:53:02
	(b) (4)	
User opened query 'PV Query: Please confirm the date of hospital admission (02 Nov 2020) which is not in accordance with the medical records,03 Nov 2020. Please update EDC accordingly.' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:10:17
	(b) (4), (b) (6)	29 Mar 2021 17:32:46
DataPoint Verified.		29 Mar 2021 17:32:23
User opened query 'please verify as 3Nov2020 per hosp record' (Site from CRA).		29 Mar 2021 16:48:47

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Form: Adverse Events (6)

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'please provide hosp records and update CM log' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:08:17
Query 'please provide hosp records and update CM log' answered with 'Hospital records have been faxed and CM updated.' (Site from CRA).	Riley King (b) (4)	25 Mar 2021 13:43:17
DataPoint Un-verified.	(b) (4)	
	Riley King (b) (4)	22 Mar 2021 21:56:54
User entered '2 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Riley King (b) (4)	22 Mar 2021 21:56:54
User opened query 'please provide hosp records and update CM log' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:46:16
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
	(b) (4)	
User entered '10 Dec 2020'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered '11 Dec 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 18:58:55
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:47:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User closed query 'PV Query: Please confirm the date of hospital discharge (23 Dec 2020) which is not in accordance with medical records, 03 Nov 2020. Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:51:36
Query 'PV Query: Please confirm the date of hospital discharge (23 Dec 2020) which is not in accordance with medical records, 03 Nov 2020. Please update EDC accordingly.' answered with 'per medication discharge summary, discharge date 11/4/2020. ' (Site from Safety).	Riley King (b) (4)	01 Apr 2021 18:55:31
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	01 Apr 2021 18:53:02
	(b) (4)	
User entered '4 Nov 2020' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 18:53:02
	(b) (4)	
User opened query 'PV Query: Please confirm the date of hospital discharge (23 Dec 2020) which is not in accordance with medical records, 03 Nov 2020. Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:10:37
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 16:41:52
DataPoint Un-verified.	Riley King (b) (4)	22 Mar 2021 21:56:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Dec 2020' reason for change: Data Entry Error	Riley King (b) (4)	22 Mar 2021 21:56:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '11 Dec 2020'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
User entered empty; reason for change Data Entry Error	marissa Mueller (b) (4)	08 Apr 2021 15:19:12
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'No (N)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered empty.	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '0'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '0'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '0'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered '0'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		09 Mar 2021 20:58:49
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	04 Mar 2021 19:20:38
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 05:31:34
User entered 'I'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'I'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User entered empty.	Riley King (b) (4)	27 Jan 2021 20:25:39
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: please consider updating date of planned percutaneous nephrostolithotomy as reported in narrative dated 10 Dec 2021 (12/10/2021) ' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 13:18:51
Query 'PV Query: please consider updating date of planned percutaneous nephrostolithotomy as reported in narrative dated 10 Dec 2021 (12/10/2021) ' answered with 'updated' (Site from Safety).	marissa Mueller (b) (4)	08 Apr 2021 19:00:17
User opened query 'PV Query: please consider updating date of planned percutaneous nephrostolithotomy as reported in narrative dated 10 Dec 2021 (12/10/2021) ' (Site from Safety).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:21:51
User signature succeeded.	(b) (4), (b) (6)	05 Apr 2021 20:47:47
	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User closed query 'PV Query: Please consider correcting the dates for planned percutaneous nephrostolithotomy which was provided as 12/10/2021 and subject released date from the hospital,12/11/2021, which is incorrect per year.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:59:26
User closed query 'PV Query: As per medical records, subject was admitted and discharged from the hospital on 03 Nov 2020. Please confirm if subject was hospitalized overnight. If not, please reassess the reported seriousness criteria of hospitalization and determine if any other seriousness criteria were met (i.e.medically significant).' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:51:44
Query 'PV Query: Please consider correcting the dates for planned percutaneous nephrostolithotomy which was provided as 12/10/2021 and subject released date from the hospital,12/11/2021, which is incorrect per year.' answered with 'reconciled ' (Site from Safety).	Riley King (b) (4)	01 Apr 2021 18:56:29
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: As per medical records, subject was admitted and discharged from the hospital on 03 Nov 2020. Please confirm if subject was hospitalized overnight. If not, please reassess the reported seriousness criteria of hospitalization and determine if any other seriousness criteria were met (i.e.medically significant).' answered with 'per medication discharge summary, discharge date 11/4/2020.' (Site from Safety). DataPoint Un-verified.	Riley King (b) (4) (b) (4)	01 Apr 2021 18:56:02
	Riley King (b) (4) (b) (4)	01 Apr 2021 18:53:02

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT STATED A RECENT HOSPITALIZATION DURING THE UNBLINDING VISIT ON 1/26/2021. SUBJECT STATED SHE WENT TO ER WITH ABDOMINAL PAIN AND WAS NOTED TO HAVE A URETERAL STONE ON 11/3/2020. SUBJECT HAD STENT PLACED AND LITHOTRIPSY. THESE METHODS FAILED TO DRAIN THE STONE. SUBJECT HAD A PLANNED PERCUTANEOUS NEPHROSTOLITHOTOMY ON 12/10/2021. THE SUBJECT WAS OBSERVED OVERNIGHT AND RELEASED WITHOUT COMPLICATIONS THE FOLLOWING DAY ON 12/11/2020. RECORDS REQUESTED FOR ANY ADDITIONAL INFORMATION. IF NEW INFORMATION BECOMES AVAILABLE, A FU REPORT WILL BE COMPLETED. 3/22/2021 RECEIVED MEDICAL RECORDS FOR SUBJECT'S HOSPITAL STAY. SUBJECT HAD A DOUBLE J STENT PLACED IN SUBJECT'S LEFT KIDNEY ON 11/3/2021. SUBJECT ALSO HAD A LITHOTRIPSY TO BREAK STONE INTO SMALLER PIECES. DOCTOR'S NOTES STATES IF SUBJECT HAS SIGNIFICANT STONE BURDEN THEN SHE WILL NEED A PCNL, SUBJECT HAS NOT REPORTED HAVING THAT PROCEDURE DONE SINCE SHE HAD THIS PROCEDURE DONE. PRIOR TO PROCEDURE SUBJECT HAD SIGNIFICANT PAIN AND RECEIVED MULTIPLE PAIN MEDICATION TO ASSIST IN CONTROLLING PAIN. SUBJECT RECEIVED IV MEDS PRIOR TO PROCEDURE. SUBJECT DID NOT HAVE ANY MEDICATIONS PRESCRIBED WHEN BEING DISCHARGED FROM THE HOSPITAL.' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	01 Apr 2021 18:53:02
User opened query 'PV Query: Please consider correcting the dates for planned percutaneous nephrostolithotomy which was provided as 12/10/2021 and subject released date from the hospital,12/11/2021, which is incorrect per year.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:12:40

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As per medical records, subject was admitted and discharged from the hospital on 03 Nov 2020. Please confirm if subject was hospitalized overnight. If not, please reassess the reported seriousness criteria of hospitalization and determine if any other seriousness criteria were met (i.e.medically significant).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:11:33
	(b) (4), (b) (6)	29 Mar 2021 16:30:54
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 19:14:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'these have been faxed.' (Site from Safety).	Riley King (b) (4)	25 Mar 2021 13:42:44
DataPoint Un-verified.	(b) (4)	
	Riley King (b) (4)	22 Mar 2021 21:56:54
	(b) (4)	

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Audit	User	Time (GMT)
User entered 'SUBJECT STATED A RECENT HOSPITALIZATION DURING THE UNBLINDING VISIT ON 1/26/2021. SUBJECT STATED SHE WENT TO ER WITH ABDOMINAL PAIN AND WAS NOTED TO HAVE A URETERAL STONE ON 11/3/2020. SUBJECT HAD STENT PLACED AND LITHOTRIPSY. THESE METHODS FAILED TO DRAIN THE STONE. SUBJECT HAD A PLANNED PERCUTANEOUS NEPHROSTOLITHOTOMY ON 12/10/2021. THE SUBJECT WAS OBSERVED OVERNIGHT AND RELEASED WITHOUT COMPLICATIONS THE FOLLOWING DAY ON 12/11/2021. RECORDS REQUESTED FOR ANY ADDITIONAL INFORMATION. IF NEW INFORMATION BECOMES AVAILABLE, A FU REPORT WILL BE COMPLETED. 3/22/2021 Received medical records for subject's hospital stay. Subject had a double J stent placed in subject's left kidney on 11/3/2021. Subject also had a lithotripsy to break stone into smaller pieces. Doctor's notes states if subject has significant stone burden then she will need a PCNL, subject has not reported having that procedure done since she had this procedure done. Prior to procedure subject had significant pain and received multiple pain medication to assist in controlling pain. Subject received IV meds prior to procedure. Subject did not have any medications prescribed when being discharged from the hospital.'	Riley King (b) (4) (b) (4)	22 Mar 2021 21:56:54
reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:32:26
User closed query 'PV Query: Per narrative, the subject was unblinded on 26 Jan 2021. If true, please update unblinding details in EDC.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 19:13:34
Query 'PV Query: Per narrative, the subject was unblinded on 26 Jan 2021. If true, please update unblinding details in EDC.' answered with 'updated' (Site from Safety).	Colton King (b) (4) (b) (4)	04 Feb 2021 19:06:26
User opened query 'PV Query: Per narrative, the subject was unblinded on 26 Jan 2021. If true, please update unblinding details in EDC.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:41:27

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Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:39:47
User entered 'Subject stated a recent hospitalization during the unblinding visit on 1/26/2021. Subject stated she went to ER with abdominal pain and was noted to have a ureteral stone on 11/3/2020. Subject had stent placed and lithotripsy. These methods failed to drain the stone. Subject had a planned Percutaneous Nephrostolithotomy on 12/10/2021. The subject was observed overnight and released without complications the following day on 12/11/2021. Records requested for any additional information. If new information becomes available, a FU report will be completed.'	Riley King (b) (4)	27 Jan 2021 20:25:39

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 18:58:55
User entered '0'	System	08 Apr 2021 15:19:12
User entered '1'	System	27 Jan 2021 20:25:39

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 20:25:39

US3062079

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Jan 2021 20:25:39

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 07:19:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 07:19:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 17:32:23
Data point term sent to Coder	System	22 Mar 2021 22:22:37
User entered 'Pain- generalized'	Riley King (b) (4)	22 Mar 2021 22:22:28
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Yes (Y)'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User entered empty.	System	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User entered empty.	System	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'I'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User entered '0'	System	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48
User entered 'I'	System	22 Mar 2021 22:22:28

US3062079

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:48

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Mar 2021 13:30:26
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Mar 2021 13:30:26
Data point term sent to Coder	System	22 Mar 2021 22:23:38
User entered 'Nausea- generalized'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Yes (Y)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User entered empty.	System	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User closed query 'please verify as 6Nov2020 per AE log' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 20:49:24
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:47:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
Query 'please verify as 6Nov2020 per AE log' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	01 Apr 2021 17:48:22
User entered '06 Nov 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	01 Apr 2021 17:48:03
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 17:33:05
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User opened query 'please verify as 6Nov2020 per AE log' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 17:30:41
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User entered empty.	System	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'I'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User entered '0'	System	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50
User entered 'I'	System	22 Mar 2021 22:23:06

US3062079

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:50

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User coded data point as SOC: Renal and urinary disorders, HLT: Urinary tract lithiasis (excl renal), PT: Calculus bladder, LLT: Bladder calculus - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 22:25:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 22:25:51
Data point term sent to Coder	System	22 Mar 2021 22:24:39
User entered 'bladder calculus'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Yes (Y)'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User entered empty.	System	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User entered empty.	System	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 16:08:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Mar 2021 16:08:50
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	23 Mar 2021 16:08:50
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 22:23:43
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:47:47
DataPoint Un-verified.	marissa Mueller (b) (4)	05 Apr 2021 16:23:00
Signature has been broken.	(b) (4) marissa Mueller (b) (4)	05 Apr 2021 16:23:00
User entered '1' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	05 Apr 2021 16:23:00
User signature succeeded.	(b) (4) Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this verbatim AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 05:15:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:47:47
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this verbatim AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	05 Apr 2021 16:23:23
DataPoint Un-verified.	marissa Mueller (b) (4) (b) (4)	05 Apr 2021 16:23:00
Signature has been broken.	marissa Mueller (b) (4) (b) (4)	05 Apr 2021 16:23:00
User entered '0' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	05 Apr 2021 16:23:00
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this verbatim AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:13:49
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User entered '0'	System	23 Mar 2021 16:08:50

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54
User entered 'I'	System	22 Mar 2021 22:23:43

US3062079

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:54

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
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)	22 Mar 2021 22:25:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 22:25:51
Data point term sent to Coder	System	22 Mar 2021 22:24:39
User entered 'urinary tract infection'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User entered empty.	System	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User entered empty.	System	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	22 Mar 2021 22:24:19

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:47:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	01 Apr 2021 19:17:08
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 19:17:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '1' reason for change: Data Entry Error	Riley King (b) (4)	29 Mar 2021 14:21:46
	(b) (4)	
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:24:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:47:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	01 Apr 2021 19:17:08
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 19:17:08
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	31 Mar 2021 10:24:29
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Riley King (b) (4)	29 Mar 2021 14:21:55
	(b) (4)	
' answered with 'reconciled ' (Site from DM).		
User entered '0' reason for change: Data Entry Error	Riley King (b) (4)	29 Mar 2021 14:21:46
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	29 Mar 2021 11:20:31
' (Site from DM).		
User entered '1'	Riley King (b) (4)	22 Mar 2021 22:24:19
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:32:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:32:23
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User entered '0'	System	22 Mar 2021 22:24:19

US3062079

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58
User entered 'I'	System	22 Mar 2021 22:24:19

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:18:58

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'USA-US090-2021-mRNA-1273-P301000012'	System	26 Apr 2021 14:00:38
User entered 'New'	(b) (4), (b) (6)	26 Apr 2021 14:00:38
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis recurrent - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:01:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:01:51
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:01:14
User entered 'Worsening of recurrent nephrolithiasis'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '19 Apr 2021'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered empty.	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:00:20
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:41:50
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered empty.	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered empty.	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:00:20
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Yes (Y)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '0'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '0'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 06:27:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject still in the hospital.' (Site from System).	Riley King (b) (4)	23 Apr 2021 16:02:28
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Apr 2021 16:00:20
User entered 'I'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '19 Apr 2021'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:59:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:40:58
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered empty.	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered empty.	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '0'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '0'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '0'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Generated On: 09 Jun 2021 14:59:21

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '0'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Generated On: 09 Jun 2021 14:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '0'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

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Generated On: 09 Jun 2021 14:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '1'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:42:16
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered empty.	Riley King (b) (4)	23 Apr 2021 16:00:20
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:42:37
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)	03 May 2021 21:42:28
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:39:50
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
User entered 'Subject was contacted to complete weekly diary, site left message for subject. Subject returned call to inform site that she is admitted to NMC health hospital for worsening of recurrent nephrolithiasis. Subject began having flank pain and went to the emergency room where she was diagnosed with nephrolithiasis. She was admitted and had a lithotripsy performed on 4/21/2021. When site staff spoke to subject, she reported that there is a possibility of discharge 4/23/2021. Release of records sent to subject to be signed and returned.'	(b) (4) Riley King (b) (4)	23 Apr 2021 16:00:20
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12

US3062079

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:00:20
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12

US3062079

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 16:00:20
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Riley King (b) (4)	22 Mar 2021 22:25:12
	(b) (4)	

US3062079

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 14:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Apr 2021 16:00:20
DataPoint activated with code reason code Data required.	Riley King (b) (4)	23 Apr 2021 15:58:17
DataPoint inactivated with code reason code Data not required.	Riley King (b) (4)	22 Mar 2021 22:25:12

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:38
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
User closed query 'please add dilaudid .5mg Inj 3Nov per hosp records' (Site from CRA).	(b) (4)	
Query 'please add dilaudid .5mg Inj 3Nov per hosp records' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	06 Apr 2021 16:03:38
User opened query 'please add dilaudid .5mg Inj 3Nov per hosp records' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 19:29:09
User closed query 'Per ETRTR: Please add Medication dates and dose for SAE Nephrolithiasis, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 17:06:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:06:10
User closed query 'Per CDM: re-query of system queries on Diary Dose 2 (1), Temperature day, Day 2, 3, 6, 7, 8. Per the participant response, medication was taken to treat pain or fever. There was a response that the concomitant medications will be updated, however there are still no matching medications. Please also note that there should have been a safety call for Day 36 yet the form is empty. Please update the ConMed eCRF, or clarify. Thank you! ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:29:29
Query 'Per CDM: re-query of system queries on Diary Dose 2 (1), Temperature day, Day 2, 3, 6, 7, 8. Per the participant response, medication was taken to treat pain or fever. There was a response that the concomitant medications will be updated, however there are still no matching medications. Please also note that there should have been a safety call for Day 36 yet the form is empty. Please update the ConMed eCRF, or clarify. Thank you! ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	28 Sep 2020 08:53:57
Query 'Per ETRTR: Please add Medication dates and dose for SAE Nephrolithiasis, thanks.' answered with 'updated' (Site from CRA).	(b) (4)	26 Sep 2020 19:29:14
User opened query 'Per ETRTR: Please add Medication dates and dose for SAE Nephrolithiasis, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 01:00:31
	(b) (4), (b) (6)	19 Sep 2020 18:43:07

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:59:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: re-query of system queries on Diary Dose 2 (1), Temperature day, Day 2, 3, 6, 7, 8. Per the participant response, medication was taken to treat pain or fever. There was a response that the concomitant medications will be updated, however there are still no matching medications. Please also note that there should have been a safety call for Day 36 yet the form is empty. Please update the ConMed eCRF, or clarify. Thank you! ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4) Janna Martinez (b) (4) (b) (4)	16 Sep 2020 10:14:45 06 Aug 2020 00:27:31

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:15:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: EQUATE STOOL SOFTENER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 14:12:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 14:12:43
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 00:31:02
User entered 'EQUATE STOOL SOFTENER'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:15:48
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:15:50
User entered 'IRRITABLE BOWEL SYNDROME-CONSTIPATION'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:15:58
User entered '1'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:08
User entered 'tablet (TABLET)'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:11
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:13
User entered 'once daily (QD)'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:19
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:21
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:24
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:27
	(b) (4), (b) (6)	11 Aug 2020 05:41:10
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:31:13
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:30:51
User entered 'UN UNK 2019'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:31
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:34
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:36
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:16:38
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:30:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:30:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:30:51

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:30:51

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:17:59
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 07:55:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 07:55:42
	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 16:51:26
Coding entries removed.	marissa Mueller (b) (4)	09 Sep 2020 16:50:37
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 00:33:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 00:33:01
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 00:32:02
User entered 'GABAPENTIN'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:01
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:04
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).		10 Sep 2020 07:40:32
Query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	09 Sep 2020 16:50:40
User entered 'NEUROPATHY-bilateral hands, unspecified' reason for change: Data Entry Error	(b) (4)	
	marissa Mueller (b) (4)	09 Sep 2020 16:50:37
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 14:54:56
User entered 'NEUROPATHY'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:06
User entered '300'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:09
User entered 'mg (mg)'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:11
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:13
User entered 'three times daily (TID)'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:19
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:23
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:26
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:29
	(b) (4), (b) (6)	11 Aug 2020 05:41:34
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:32:01
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:31:56
User entered 'UN Jan 2020'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:32
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:36
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:41
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:18:43
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:31:56
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Aug 2020 00:31:56

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:31:56

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:31:56

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:19:14
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 11:46:14
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 11:46:14
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 00:36:57
User entered 'MICROGESTIN FE 1/20' reason for change: Data Entry Error	Sherry Henning (b) (4)	08 Aug 2020 00:36:26
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 00:34:04
User entered 'MICROGESTIN FE'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:19:16
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:22
User entered 'CONTRCEPTION'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:23
User entered '1' reason for change: Data Entry Error	Sherry Henning (b) (4)	08 Aug 2020 00:36:26
	(b) (4)	
User entered '1/20'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:25
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 00:36:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 00:36:26
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Sherry Henning (b) (4)	08 Aug 2020 00:36:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 00:33:32
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:27
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:29
User entered 'once daily (QD)'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:32
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:37
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:40
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:42
	(b) (4), (b) (6)	11 Aug 2020 05:43:06
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:33:48
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:33:32
User entered 'un UNK 2018'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:46
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:48
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:49
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:20:52
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:33:32
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:33:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:33:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:33:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:53
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 00:36:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 00:36:04
Data point term sent to Coder	System	06 Aug 2020 00:35:05
User entered 'TRAZADONE'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:56
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:21:58
User entered 'INSOMNIA'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:00
User entered '150'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:03
User entered 'mg (mg)'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:05
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:08
User entered 'once daily (QD)'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:14
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:16
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:18
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:23
	(b) (4), (b) (6)	11 Aug 2020 05:43:23
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:34:35
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:34:31
User entered 'UN UNK 2013'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:26
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:28
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:35
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 21:22:33
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:34:31
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:34:31

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:34:31

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:34:31

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VILAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: VIIBRYD - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 00:42:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 00:42:00
Data point term sent to Coder	System	06 Aug 2020 00:41:12
User entered 'VIIBRYD'	Janna Martinez (b) (4) (b) (4)	06 Aug 2020 00:40:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:10
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:18
User entered 'BIPOLAR DEPRESSION'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User closed query 'please verify dose as 20mg as per source' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 16:31:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:31:15
	(b) (4)	
Query 'please verify dose as 20mg as per source' answered with 'updated' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 19:33:02
	(b) (4)	
User entered '20' reason for change: Data Entry Error	marissa Mueller (b) (4)	22 Oct 2020 19:32:56
	(b) (4)	
User opened query 'please verify dose as 20mg as per source' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:20:37
	(b) (4)	
User entered '120'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:21
User entered 'mg (mg)'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:24
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:26
User entered 'once daily (QD)'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:34
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:39
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:42
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:46
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 05:43:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:40:35
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:40:30
User entered 'UN UNK 2013'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:48
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:52
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:54
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:24:56
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:40:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:40:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:40:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:40:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: PROPRANOLOL HYDROCHLORIDE, PRODUCTSYNONYM: INDERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:47:01
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:47:01
Data point term sent to Coder	System	06 Aug 2020 00:42:13
User entered 'INDERAL'	Janna Martinez (b) (4) (b) (4)	06 Aug 2020 00:42:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:09
Un-reviewed for Data Management.	(b) (4), (b) (6)	02 Sep 2020 14:55:38
Reviewed for Data Management.	(b) (4), (b) (6)	02 Sep 2020 14:55:34
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:27:46
	(b) (4), (b) (6)	10 Sep 2020 07:41:24
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' (Site from DM). Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	09 Sep 2020 16:51:11
	(b) (4)	
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 14:55:41
User entered 'MIGRAINES'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:15
User entered '20'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:17
User entered 'mg (mg)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:19
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:22
User entered 'three times daily (TID)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:26
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:29
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:31
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:36
	(b) (4), (b) (6)	11 Aug 2020 05:44:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:42:12
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:42:08
User entered 'UN UNK 2013'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:41
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:43
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:46
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:26:48
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Aug 2020 00:42:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:42:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:42:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 12:32:06
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 12:32:06
Data point term sent to Coder	System	06 Aug 2020 00:43:13
User entered 'LAMICTAL'	Janna Martinez (b) (4) (b) (4)	06 Aug 2020 00:42:55

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:15
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:17
User entered 'ANXIETY'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:19
User entered '200'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:21
User entered 'mg (mg)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:22
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:24
User entered 'once daily (QD)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:29
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:30
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:33
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:35
	(b) (4), (b) (6)	11 Aug 2020 05:44:18
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:42:59
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:42:55
User entered 'UN UNK 2013'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:38
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:41
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:45
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:28:48
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:42:55

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:42:55

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:42:55

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 00:46:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 00:46:02
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 00:45:14
User entered 'BUSPIRONE'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:16
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:18
User entered 'ANXIETY'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:24
	(b) (4), (b) (6)	04 Nov 2020 20:55:15
User closed query 'please verify dose as per hospital discharge summary' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 23:09:05
Query 'please verify dose as per hospital discharge summary' answered with 'verbally verified with patient' (Site from CRA).	(b) (4)	
User opened query 'please verify dose as per hospital discharge summary' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:31:07
User entered '15'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:20
User entered 'mg (mg)'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:23
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:37:19
User entered 'twice daily (BID)'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:32
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:33
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:36
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:38
	(b) (4), (b) (6)	11 Aug 2020 05:44:39
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:44:54
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:44:33
User entered 'UN UNK 2013'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:39
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:50
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:53
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:31:56
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:44:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Aug 2020 00:44:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:44:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:44:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFIXIME, PRODUCTSYNONYM: FLEXERIL [CEFIXIME] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:26:38
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:26:38
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	22 Oct 2020 16:51:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFIXIME, PRODUCTSYNONYM: FLEXERIL [CEFIXIME] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 23:12:15
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 23:12:15
Data point term sent to Coder	System	06 Aug 2020 00:46:19
User entered 'FLEXERIL'	Janna Martinez (b) (4) (b) (4)	06 Aug 2020 00:46:09

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:26
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:28
User entered 'MUSCLE SPASMS LEGS'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:30
User entered '10'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:32
User entered 'mg (mg)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:34
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:35
User entered 'once daily (QD)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:37
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:42
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:44
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:47
	(b) (4), (b) (6)	11 Aug 2020 05:45:06
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:46:17
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:46:09
User entered 'UN UNK 2019'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:50
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:53
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:54
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:51:58
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:09
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:46:09

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:46:09

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:46:09

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:19
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)	06 Aug 2020 00:48:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 00:48:03
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 00:47:19
User entered 'MULTIVITAMIN'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:21
	(b) (4), (b) (6)	
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 16:06:24
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	Justin Phillips (b) (4)	15 Sep 2020 00:25:33
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Justin Phillips (b) (4)	15 Sep 2020 00:25:24
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 11:22:13
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:24
User entered 'NUTRITIONAL SUPPLEMENT'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:26
User entered '1'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:29
User entered 'tablet (TABLET)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:31
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:33
User entered 'once daily (QD)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:38
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:40
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:47
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:48
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		11 Aug 2020 05:45:56
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Janna Martinez (b) (4)	06 Aug 2020 00:46:56
answered with 'DATA CORRECT AS ENTERED' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 00:46:52
User entered 'UN Mar 2020'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:55:57
User entered '0'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:56:00
User entered 'Yes (Y)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:56:02
User entered empty.	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:56:04
User entered 'No (N)'	Janna Martinez (b) (4)	06 Aug 2020 00:46:52
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:46:52

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 00:46:52

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 00:46:52

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:05:55
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 Apr 2021 17:05:55
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:56:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:00:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:00:44
Data point term sent to Coder	System	24 Sep 2020 20:38:18
User entered 'normal saline'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:56:55
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:56:58
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:25:34
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 17:24:44
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:57:00
User entered '1000'	marissa Mueller (b) (4)	24 Sep 2020 20:37:40
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:57:09
User entered 'mL (mL)'	marissa Mueller (b) (4)	24 Sep 2020 20:37:40
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:58:37
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:37:40
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 17:24:49
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:58:39
User entered 'once (ONCE)'	marissa Mueller (b) (4)	24 Sep 2020 20:37:40
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:58:41
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 16:58:46
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	24 Sep 2020 20:37:40
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:58:49
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
Query 'please correct start date on CM log (per hosp records, IV started on 7Sep)' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:59:18
User opened query 'please correct start date on CM log (per hosp records, IV started on 7Sep)' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:02:01
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:01:28
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:37:40
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:01:33
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:37:40
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:58:58
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:59:23
Query 'please verify stop date as 9Sep as per CM log' canceled (Site from CRA).		22 Oct 2020 17:59:21
User opened query 'please verify stop date as 9Sep as per CM log' (Site from CRA).		22 Oct 2020 17:02:54
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:37:40
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:59:07
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User entered empty.	System	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User entered empty.	System	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:59:51
User entered empty.	System	24 Sep 2020 20:37:40

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:07:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 06:01:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 06:01:40
Data point term sent to Coder	System	24 Sep 2020 20:39:19
User entered 'norco 5/325mg'	marissa Mueller (b) (4)	24 Sep 2020 20:38:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:07:51
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:07:54
User entered 'post op pain'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:07:56
User entered 'I'	marissa Mueller (b) (4)	24 Sep 2020 20:38:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:07:59
User entered 'tablet (TABLET)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:08:03
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:38:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:08:05
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:04:17
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:08:11
User entered 'Oral (ORAL)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:04:14
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:38:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	17 Nov 2020 14:40:35
Query 'please correct start date on CM log (date of procedure = 9/9 per hosp record' canceled (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:38:27
User opened query 'please correct start date on CM log (date of procedure = 9/9 per hosp record' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:04:11
User entered '09 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:38:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:07:31
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:38:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:52:36
DataPoint Un-verified.	marissa Mueller (b) (4)	22 Oct 2020 19:34:42
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	22 Oct 2020 19:34:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:07:34
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 20:38:30
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:52:39
User closed query 'please verify 16Sep2020 as per CM log' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:52:31
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	22 Oct 2020 19:34:42
Query 'please verify 16Sep2020 as per CM log' answered with 'udpted' (Site from CRA).	marissa Mueller (b) (4) (b) (4)	22 Oct 2020 19:34:39
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	22 Oct 2020 19:34:34
User entered '16 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	22 Oct 2020 19:34:34
User opened query 'please verify 16Sep2020 as per CM log' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:39:08
DataPoint Un-verified.		22 Oct 2020 17:38:33
DataPoint Verified.		22 Oct 2020 17:07:36
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:07:40
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User entered empty.	System	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User entered empty.	System	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:04
User entered empty.	System	24 Sep 2020 20:38:30

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:09:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:29:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:29:44
Data point term sent to Coder	System	24 Sep 2020 20:40:20
User entered 'compazine'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:09:34
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:09:36
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:20:44
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'Given during hospitalization for Bilateral nephrolithiasis for symptom of bilateral nephrolithiasis' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 20:50:33
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:51:15
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:09:48
User entered '10'	marissa Mueller (b) (4)	24 Sep 2020 20:39:22
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:09:51
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:09:55
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:09:57
User entered 'once (ONCE)'	marissa Mueller (b) (4)	24 Sep 2020 20:39:22
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:10:00
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:39:22
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:03
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:06
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:39:22
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:10:08
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:39:22
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:18
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:15:41
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:16:18
User entered '07 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:16:21
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:39:22
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User entered empty.	System	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User entered empty.	System	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:13
User entered empty.	System	24 Sep 2020 20:39:22

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:05:55
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 Apr 2021 17:05:55
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:16:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:00:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 06:00:44
Data point term sent to Coder	System	24 Sep 2020 20:40:23
User entered 'normal saline'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:16:36
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:17:40
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:00:22
Query 'Dose entered does not match CM log, please reconcile' canceled (Site from CRA).		22 Oct 2020 18:00:20
User opened query 'Dose entered does not match CM log, please reconcile' (Site from CRA).		22 Oct 2020 17:28:53
User entered '125'	marissa Mueller (b) (4)	24 Sep 2020 20:40:17
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:00:24
User entered 'mL (mL)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:00:27
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:40:17
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:17:57
User entered 'other (OTHER)'	marissa Mueller (b) (4)	24 Sep 2020 20:40:17
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:00:29
User entered 'once/ hour'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:00:34
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	24 Sep 2020 20:40:17
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:00:36
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:18:45
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:40:17
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:00:41
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 18:00:43
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:40:17
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:00:46
User entered '10 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:40:17
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:00:48
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User entered empty.	System	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User entered empty.	System	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:44
User entered empty.	System	24 Sep 2020 20:40:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:29:32
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: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 07:24:41
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 Sep 2020 07:24:41
Data point term sent to Coder	System	24 Sep 2020 20:41:24
User entered 'Flomax'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:29:33
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:29:35
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:21:22
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'Given during hospitalization for bilateral nephrolithiasis ' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 20:47:55
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:51:33
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:29:38
User entered '0.4'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:29:40
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:30:44
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:40:46
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:30:48
User entered 'once daily (QD)'	marissa Mueller (b) (4)	24 Sep 2020 20:40:46
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:30:50
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:30:52
User entered 'Oral (ORAL)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:30:54
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:30:55
User entered '07 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:30:57
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:31:00
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:31:02
User entered '10 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:40:46
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:31:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:40:46
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User entered '1'	System	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User entered '1'	System	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:49
User entered '804 (804)'	System	24 Sep 2020 20:40:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:32:29
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)	25 Sep 2020 06:04:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 06:04:46
Data point term sent to Coder	System	24 Sep 2020 20:41:26
User entered 'morphine'	marissa Mueller (b) (4)	24 Sep 2020 20:41:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:32:31
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:41:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:32:34
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:53:38
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:51:41
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:32:36
User entered '2'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:32:38
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:32:41
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:41:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:32:43
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:32:46
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:32:56
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:32:54
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:32:59
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:41:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:33:02
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:41:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:33:04
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:33:06
User entered '10 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:33:09
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:41:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User entered empty.	System	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User entered empty.	System	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:59
User entered empty.	System	24 Sep 2020 20:41:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:39:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 06:01:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 06:01:40
Data point term sent to Coder	System	24 Sep 2020 20:43:29
User entered 'norco 5/325mg'	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:39:28
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:39:30
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:53:35
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:51:49
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:39:32
User entered 'I'	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:39:34
User entered 'tablet (TABLET)'	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:39:36
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:39:38
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:39:40
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:39:44
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:39:47
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:39:50
User entered '07 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:39:52
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:39:58
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:40:00
User entered '09 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:40:05
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:42:29
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User entered empty.	System	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User entered empty.	System	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:04
User entered empty.	System	24 Sep 2020 20:42:29

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User closed query 'please verify use of Colace 100mg PO q HS per hospital discharge summary' (Site from CRA).	(b) (4)	04 Nov 2020 20:54:23
Query 'please verify use of Colace 100mg PO q HS per hospital discharge summary' answered with 'corret per patient report' (Site from CRA).	marissa Mueller (b) (4)	22 Oct 2020 23:12:49
User opened query 'please verify use of Colace 100mg PO q HS per hospital discharge summary' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 17:43:17
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:40:36
User closed query 'Per DM CLR: Con Med was added during the study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:22:36
Query 'Per DM CLR: Con Med was added during the study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'No worsening. Subject was given opioid during hospitalization. ' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 20:51:27
User opened query 'Per DM CLR: Con Med was added during the study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:52:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 05:38:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 20:43:29
User entered 'sennosides/docusate sodium (8.6mg/50mg)'	marissa Mueller (b) (4)	24 Sep 2020 20:43:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:40:38
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:40:58
User entered 'IBS- constipation'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:00
User entered 'I'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:02
User entered 'tablet (TABLET)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:08
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:43:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:17
User entered 'twice daily (BID)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:19
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:23
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	24 Sep 2020 20:43:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:26
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:43:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:33
User entered '07 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:35
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:39
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:43:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:41:41
User entered '10 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:43:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:41:44
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:43:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 20:43:19
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:19
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:43:16
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User entered '2'	System	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User entered '1'	System	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:22
User entered '804 (804)'	System	24 Sep 2020 20:43:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:43:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 20:45:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 20:45:39
Data point term sent to Coder	System	24 Sep 2020 20:44:30
User entered 'dilaudid'	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:43:32
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:43:35
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:23:44
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'This is correct as entered' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 20:51:50
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:52:14
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:43:39
User entered 'I'	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:43:42
User entered 'mg (mg)'	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:43:44
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:43:49
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:43:58
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:44:00
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:44:03
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:44:05
User entered '09 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:07
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:10
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:12
User entered '09 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:43:48
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:44:15
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User entered empty.	System	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User entered empty.	System	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:01:28
User entered empty.	System	24 Sep 2020 20:43:48

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 20:45:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 20:45:38
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 20:44:31
User entered 'miralax'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:30
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:33
User entered 'IBS- constipation'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:40
User entered '17'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:47
User entered 'g (g)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:49
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:52
User entered 'as needed (PRN)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:54
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:45:02
User entered 'Oral (ORAL)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:44:58
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:45:06
User entered 'un UNK 2019'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:45:08
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:45:10
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:45:13
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:45:15
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:19
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 20:44:19

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 20:44:19

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 20:44:19

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:45:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LOVENOX [LEVOFLOXACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 06:12:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 06:12:39
Data point term sent to Coder	System	24 Sep 2020 20:45:32
User entered 'lovenox'	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:45:27
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:54:27
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:46:16
DataPoint Un-verified.		22 Oct 2020 17:46:14
DataPoint Verified.		22 Oct 2020 17:45:29
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'Given during hospitalization for Bilateral nephrolithiasis for prophylaxis' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 20:52:30
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:52:28
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:46:18
User entered '40'	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:46:20
User entered 'mg (mg)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:46:22
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:46:26
User entered 'once daily (QD)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:46:29
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:46:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:46:36
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:46:39
User entered '08 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:46:44
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:46:49
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:46:52
User entered '10 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:46:54
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:44:47
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User entered '1'	System	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User entered '1'	System	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:23
User entered '804 (804)'	System	24 Sep 2020 20:44:47

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:47:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFZOLIN SODIUM, PRODUCTSYNONYM: KEFZOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:13:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:13:20
Data point term sent to Coder	System	08 Oct 2020 14:48:28
Coding entries removed.	Sherry Henning (b) (4) (b) (4)	08 Oct 2020 14:47:44
User entered 'KEFzol' reason for change: Data Entry Error	Sherry Henning (b) (4) (b) (4)	08 Oct 2020 14:47:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 23:12:41
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 23:12:41
Data point term sent to Coder	System	24 Sep 2020 20:45:33
User entered 'keflex'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:47:11
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:47:14
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:25:13
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'Correct as entered. ' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 20:53:04
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:54:25
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:47:25
User entered 'I'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:47:27
User entered 'g (g)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:47:29
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:47:33
User entered 'once daily (QD)'	marissa Mueller (b) (4)	24 Sep 2020 20:45:15
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:51:59
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:52:02
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4)	24 Sep 2020 20:45:15
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:52:04
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:45:15
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:52:06
User entered '09 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:52:08
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:45:15
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:52:10
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:52:43
User entered '09 Sep 2020'	marissa Mueller (b) (4)	24 Sep 2020 20:45:15
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:52:45
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User entered '1'	System	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User entered '1'	System	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:31
User entered '804 (804)'	System	24 Sep 2020 20:45:15

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:34
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 20:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 20:47:42
Data point term sent to Coder	System	24 Sep 2020 20:46:34
User entered 'omnipaque'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:36
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:38
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:25:07
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'Given for procedure for bilateral nephrolithiasis' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 20:53:30
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:54:35
User entered 'bilateral nephrolithiasis'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:53:40
User entered '4'	marissa Mueller (b) (4)	24 Sep 2020 20:46:04
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:42
User entered 'mL (mL)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:44
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:46:04
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:46
User entered 'once daily (QD)'	marissa Mueller (b) (4)	24 Sep 2020 20:46:04
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:51
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:46:04
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:53
User entered 'Intravenous (INTRAVENOUS)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:54
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:46:04
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:57
User entered '09 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:53:59
User entered '0'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:01
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:46:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 20:46:08
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 20:46:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	24 Sep 2020 20:46:04
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:03
User entered '09 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:06
User entered 'No (N)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User entered '1'	System	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User entered '1'	System	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:10:41
User entered '804 (804)'	System	24 Sep 2020 20:46:04

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:14
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 20:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 20:47:42
Data point term sent to Coder	System	24 Sep 2020 20:46:36
User entered 'mucinex'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:54:21
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:46:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:23
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:35:06
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	13 Oct 2020 01:11:04
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:55:15
User entered 'seasonal allergies'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:27
User entered '600'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:54:33
User entered 'mg (mg)'	marissa Mueller (b) (4)	24 Sep 2020 20:46:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:54:35
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:46:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:40
User entered 'as needed (PRN)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:54:42
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:46:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:44
User entered 'Oral (ORAL)'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:46
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:48
User entered '08 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:54:50
User entered '0'	marissa Mueller (b) (4)	24 Sep 2020 20:46:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:54:52
User entered 'Yes (Y)'	marissa Mueller (b) (4)	24 Sep 2020 20:46:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:54:56
User entered empty.	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:54:58
User entered 'No (N)'	marissa Mueller (b) (4)	24 Sep 2020 20:46:33
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User entered empty.	System	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User entered empty.	System	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 05:16:59
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:48
User entered empty.	System	24 Sep 2020 20:46:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 17:56:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 14:55:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	29 Sep 2020 14:55:40
Data point term sent to Coder	System	25 Sep 2020 16:00:16
User entered 'Lactated Ringer's solution'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:56:10
User entered 'No (N)'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:12
User entered 'bilateral nephrolithiasis'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:14
User entered '50'	Janna Martinez (b) (4) (b) (4)	25 Sep 2020 15:59:25

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:17
User entered 'mL (mL)'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:19
User entered empty.	Janna Martinez (b) (4) (b) (4)	25 Sep 2020 15:59:25

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:21
User entered 'other (OTHER)'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 17:56:24
User entered 'every hour'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:28
User entered 'Intravenous (INTRAVENOUS)'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:30
User entered empty.	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:33
User entered '09 Sep 2020'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:34
User entered '0'	Janna Martinez (b) (4) (b) (4)	25 Sep 2020 15:59:25

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:37
User entered 'No (N)'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:39
User entered '09 Sep 2020'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 17:56:41
User entered 'No (N)'	Janna Martinez (b) (4)	25 Sep 2020 15:59:25
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User entered empty.	System	25 Sep 2020 15:59:25

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User entered empty.	System	25 Sep 2020 15:59:25

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:13
User entered empty.	System	25 Sep 2020 15:59:25

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:53:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:53:53
Data point term sent to Coder	System	25 Sep 2020 16:01:20
User entered 'Tylenol'	Janna Martinez (b) (4) (b) (4)	25 Sep 2020 16:00:57

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:30
User entered 'No (N)'	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:33
User entered 'headache'	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:35
User entered '500'	Janna Martinez (b) (4) (b) (4)	25 Sep 2020 16:00:57

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:37
User entered 'mg (mg)'	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:39
User entered empty.	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 18:01:43
User entered 'as needed (PRN)'	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:47
User entered empty.	Janna Martinez (b) (4) (b) (4)	25 Sep 2020 16:00:57

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:01:53
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:56
User entered empty.	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:01:59
User entered '05 Sep 2020'	Janna Martinez (b) (4) (b) (4)	25 Sep 2020 16:00:57

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:02:15
User entered '0'	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:02:17
User entered 'No (N)'	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:02:20
User entered '11 Sep 2020' reason for change: Data Entry Error	marissa Mueller (b) (4)	26 Sep 2020 19:30:18
	(b) (4)	
User entered '06 Sep 2020'	Janna Martinez (b) (4)	25 Sep 2020 16:00:57
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:02:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:32:22
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Headache did not meet AE criteria' (Site from DM).	Jeri King (b) (4)	14 Oct 2020 20:54:33

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	09 Oct 2020 06:55:42
	Janna Martinez (b) (4) (b) (4)	25 Sep 2020 16:00:57

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User entered empty.	System	25 Sep 2020 16:00:57

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User entered empty.	System	25 Sep 2020 16:00:57

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:47
User entered empty.	System	25 Sep 2020 16:00:57

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPIRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:43:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:43:39
Data point term sent to Coder	System	30 Sep 2020 20:42:54
User entered 'ABILIFY'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:12
User entered 'No (N)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:15
User entered 'BIPOLAR DEPRESSION'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:17
User entered '5'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:19
User entered 'mg (mg)'	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:21
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:03:22
User entered 'once daily (QD)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:24
User entered empty.	Janna Martinez (b) (4) (b) (4)	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:03:29
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:31
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:03:33
User entered '13 May 2020'	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:35
User entered '0'	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:38
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 20:42:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 20:42:19
User entered 'No (N)' reason for change: Data Entry Error	Janna Martinez (b) (4)	30 Sep 2020 20:42:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	30 Sep 2020 20:42:10
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:40
User entered '29 Sep 2020'	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:03:42
User entered 'No (N)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:10
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User entered '1'	System	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User entered '1'	System	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:34:50
User entered '804 (804)'	System	30 Sep 2020 20:42:10

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:43:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 20:43:39
Data point term sent to Coder	System	30 Sep 2020 20:42:56
User entered 'ABILIFY'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:03
User entered 'No (N)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:05
User entered 'BIPOLAR DEPRESSION'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:07
User entered '10'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:09
User entered 'mg (mg)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:11
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:13
User entered 'once daily (QD)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:15
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:20
User entered 'Oral (ORAL)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:22
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:24
User entered '30 Sep 2020'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:27
User entered '0'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:30
User entered 'Yes (Y)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:43
User entered empty.	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:04:46
User entered 'No (N)'	Janna Martinez (b) (4)	30 Sep 2020 20:42:55
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:42:55

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 20:42:55

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 20:42:55

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User closed query 'please add zofran 4mg IV 7Sep per CM log' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 14:07:12
Query 'please add zofran 4mg IV 7Sep per CM log' answered with 'added ' (Site from CRA).	Riley King (b) (4)	18 Mar 2021 20:50:10
User opened query 'please add zofran 4mg IV 7Sep per CM log' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:38:30
	(b) (4), (b) (6)	18 Mar 2021 15:37:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 19:26:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 19:26:07
	(b) (4)	
Data point term sent to Coder	System	04 Mar 2021 19:25:22
Coding entries removed.	Colton King (b) (4)	04 Mar 2021 19:24:36
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 20:27:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 20:27:06
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 20:26:58
User entered 'Norco'	Riley King (b) (4)	27 Jan 2021 20:26:35
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered 'No (N)'	Riley King (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered 'WORSENING OF RECURRENT NEPHROLITHIASIS' reason for change: Data Entry Error	Colton King (b) (4) (b) (4)	04 Mar 2021 19:24:36
User entered 'Ureteral Stone'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered '5/325'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered empty.	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered 'as needed (PRN)'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered empty.	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered 'Oral (ORAL)'	Riley King (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered empty.	Riley King (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered '0'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered 'No (N)'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered '11 Dec 2020'	Riley King (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:37:43
User entered 'No (N)'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User entered empty.	System	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User entered empty.	System	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:15
User entered empty.	System	27 Jan 2021 20:26:35

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 16:56:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 07:44:56
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 07:44:56
Data point term sent to Coder	System	18 Mar 2021 20:50:30
User entered 'Zofran'	Riley King (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'bilateral nephrolithiasis'	Riley King (b) (4) (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered '4'	Riley King (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '7 Sep 2020'	Riley King (b) (4) (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '7 Sep 2020'	Riley King (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User entered empty.	System	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User entered empty.	System	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:21
User entered empty.	System	18 Mar 2021 20:49:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:06:41
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 Apr 2021 17:06:41
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 05:22:25
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 05:22:25
Data point term sent to Coder	System	22 Mar 2021 22:27:44
User entered 'normal saline'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '10'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mL (mL)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'twice daily (BID)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User entered '2'	System	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User entered '1'	System	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:09
User entered '804 (804)'	System	22 Mar 2021 22:26:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:01
User closed query 'please add 1% per hosp record' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:55:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: XYLOCAINE [LIDOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:51:47
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:51:47
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
Data point term sent to Coder	System	01 Apr 2021 19:00:21
Query 'please add 1% per hosp record' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4) (b) (4)	01 Apr 2021 19:00:06
Coding entries removed.	Riley King (b) (4) (b) (4)	01 Apr 2021 18:59:45
User entered 'XYLOCAINE(1%)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	01 Apr 2021 18:59:45
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:50
DataPoint Verified.		29 Mar 2021 17:17:26
User opened query 'please add 1% per hosp record' (Site from CRA).		29 Mar 2021 16:59:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE, PRODUCTSYNONYM: XYLOCAINE [LIDOCAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 06:46:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 06:46:31
Data point term sent to Coder	System	22 Mar 2021 22:27:44
User entered 'xylocaine'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User closed query 'please verify as .2 mL per hosp record' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:56:49
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:56:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
Query 'please verify as .2 mL per hosp record' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	01 Apr 2021 19:00:40
DataPoint Un-verified.	(b) (4)	
	Riley King (b) (4)	01 Apr 2021 18:59:45
	(b) (4)	
User entered '0.2' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 18:59:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User opened query 'please verify as .2 mL per hosp record' (Site from CRA).		29 Mar 2021 17:00:43
User entered '2'	Riley King (b) (4)	22 Mar 2021 22:27:36
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mL (mL)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User closed query 'please verify as subcutaneous per hosp record' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 15:57:26
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:57:02
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
Query 'please verify as subcutaneous per hosp record' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4)	01 Apr 2021 19:01:14
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4)	01 Apr 2021 18:59:45
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:54
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User opened query 'please verify as subcutaneous per hosp record' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 17:00:09
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4)	22 Mar 2021 22:27:36
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:02:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User entered empty.	System	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User entered empty.	System	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:18
User entered empty.	System	22 Mar 2021 22:27:36

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 22:29:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	22 Mar 2021 22:29:51
Data point term sent to Coder	System	22 Mar 2021 22:28:45
User entered 'lactated ringers'	Riley King (b) (4)	22 Mar 2021 22:28:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '1000'	Riley King (b) (4)	22 Mar 2021 22:28:20
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mL (mL)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'other (OTHER)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '150 ml per hour'	Riley King (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:28:20
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User entered empty.	System	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User entered empty.	System	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:27
User entered empty.	System	22 Mar 2021 22:28:20

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:03:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:03:31
Data point term sent to Coder	System	22 Mar 2021 22:29:45
User entered 'versed'	Riley King (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '2'	Riley King (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:28:53
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:28:53
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User entered empty.	System	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User entered empty.	System	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:38
User entered empty.	System	22 Mar 2021 22:28:53

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CARTILAGE;HYALURONIC ACID, PRODUCTSYNONYM: MOVE FREE ULTRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:21:15
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:21:15
Data point term sent to Coder	System	23 Mar 2021 19:23:30
Data point term sent to Coder	System	22 Mar 2021 22:29:45
User entered 'scopolamine'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Nausea, generalized' reason for change: Data Entry Error	Sherry Henning (b) (4)	23 Mar 2021 19:22:55
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'I'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'other (OTHER)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'once every 3 days'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Transdermal (TRANSDERMAL)'	Riley King (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:29:39
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '6 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User entered empty.	System	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User entered empty.	System	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:44
User entered empty.	System	22 Mar 2021 22:29:39

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User closed query 'please add zofran 4mg sublingual on 3Nov per hosp record' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:08:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
Query 'please add zofran 4mg sublingual on 3Nov per hosp record' answered with 'added ' (Site from CRA).	(b) (4) Riley King (b) (4)	01 Apr 2021 19:08:06
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User opened query 'please add zofran 4mg sublingual on 3Nov per hosp record' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 17:09:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 06:10:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	23 Mar 2021 06:10:31
Data point term sent to Coder	System	22 Mar 2021 22:30:47
User entered 'Zofran'	Riley King (b) (4)	22 Mar 2021 22:30:16
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'nausea- generalized'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '4'	Riley King (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'as needed (PRN)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User entered empty.	System	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User entered empty.	System	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:54
User entered empty.	System	22 Mar 2021 22:30:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:11:52
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:11:52
Data point term sent to Coder	System	22 Mar 2021 22:31:48
User entered 'dexamethasone'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:09:37
User closed query 'please verify as 4mg per hosp record' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:09:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
Query 'please verify as 4mg per hosp record' answered with 'per page 4 of medication record dose was 10 mg.' (Site from CRA).	Riley King (b) (4)	01 Apr 2021 19:13:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 17:18:21
DataPoint Verified.		29 Mar 2021 17:17:26
User opened query 'please verify as 4mg per hosp record' (Site from CRA).		29 Mar 2021 17:10:18
User entered '10'	Riley King (b) (4)	22 Mar 2021 22:30:59
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User entered empty.	System	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User entered empty.	System	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:11
User entered empty.	System	22 Mar 2021 22:30:59

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:22:52
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:22:52
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
Data point term sent to Coder	System	01 Apr 2021 19:16:52
Coding entries removed.	Riley King (b) (4) (b) (4)	01 Apr 2021 19:15:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:06:33
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 09:06:33
Data point term sent to Coder	System	22 Mar 2021 22:32:49
User entered 'cefazolin'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition (AE #10 URINARY TRACT INFECTION) recorded in the AE eCRF. Please review if the response and the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:37:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition (AE #10 URINARY TRACT INFECTION) recorded in the AE eCRF. Please review if the response and the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.'	(b) (4)	
answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	01 Apr 2021 19:16:17
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition (AE #10 URINARY TRACT INFECTION) recorded in the AE eCRF. Please review if the response and the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 17:17:26
	Riley King (b) (4)	22 Mar 2021 22:32:00
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:27:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	01 Apr 2021 19:15:55
	(b) (4)	
User entered 'Urinary tract infection' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 19:15:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'infection prophylaxis'	Riley King (b) (4)	22 Mar 2021 22:32:00
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'I'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'g (g)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User entered empty.	System	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User entered empty.	System	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:36
User entered empty.	System	22 Mar 2021 22:32:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: CHOLINE DERIVATIVES, PRODUCT: SUXAMETHONIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:45:51
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:45:51
Data point term sent to Coder	System	22 Mar 2021 22:33:51
User entered 'suxamethonium chloride'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '100'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User entered empty.	System	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User entered empty.	System	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:38:43
User entered empty.	System	22 Mar 2021 22:33:01

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:20
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
Data point term sent to Coder	System	22 Mar 2021 22:33:51
User entered 'fentanyl'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'pain- generalized'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '250'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'ug (ug)'	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User entered empty.	System	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User entered empty.	System	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:47
User entered empty.	System	22 Mar 2021 22:33:46

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:59:01
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:59:01
Data point term sent to Coder	System	22 Mar 2021 22:34:52
User entered 'Propofol'	Riley King (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '200'	Riley King (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4)	22 Mar 2021 22:34:26
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User entered empty.	System	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User entered empty.	System	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:41:58
User entered empty.	System	22 Mar 2021 22:34:26

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:45:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:45:31
Data point term sent to Coder	System	22 Mar 2021 22:35:55
User entered 'phenylephrine'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'I'	Riley King (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User entered empty.	System	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User entered empty.	System	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:23
User entered empty.	System	22 Mar 2021 22:35:32

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:05:55
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 Apr 2021 17:05:55
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 05:22:25
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 05:22:25
Data point term sent to Coder	System	22 Mar 2021 22:36:56
User entered 'normal saline'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '1000'	Riley King (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
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) (6)	06 Apr 2021 04:32:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:51:06
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
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 'reconciled ' (Site from DM).	Riley King (b) (4)	01 Apr 2021 19:18:23
DataPoint Un-verified.	Riley King (b) (4)	01 Apr 2021 19:18:15
User entered 'mL (mL)' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 19:18:15
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)	30 Mar 2021 19:08:42
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'other (OTHER)'	Riley King (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '125 ml per hour'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User entered empty.	System	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User entered empty.	System	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:42:29
User entered empty.	System	22 Mar 2021 22:36:16

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: PETHIDINE HYDROCHLORIDE, PRODUCTSYNONYM: DEMEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 22:38:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 22:38:51
Data point term sent to Coder	System	22 Mar 2021 22:37:57
User entered 'Demerol'	Riley King (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'pain- generalized'	Riley King (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '12.5'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'as needed (PRN)'	Riley King (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User entered empty.	System	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User entered empty.	System	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:53
User entered empty.	System	22 Mar 2021 22:37:00

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, PRODUCT: ATROPA BELLADONNA EXTRACT;PAPAVER SOMNIFERUM POWDER, PRODUCTSYNONYM: BELLADONNA & OPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 11:46:25
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 11:46:25
Data point term sent to Coder	System	22 Mar 2021 22:37:57
User entered 'belladonna-opium'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'pain generalized'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:56:18
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:41:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	01 Apr 2021 19:20:44
DataPoint Un-verified.	Riley King (b) (4)	01 Apr 2021 19:20:10
User entered '30/16.2' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 19:20:10
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:10:31
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '30'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Rectal (RECTAL)'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User entered empty.	System	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User entered empty.	System	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:03
User entered empty.	System	22 Mar 2021 22:37:45

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:04:30
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:04:30
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:11:07
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
Data point term sent to Coder	System	01 Apr 2021 19:21:57
Coding entries removed.	Riley King (b) (4) (b) (4)	01 Apr 2021 19:21:40
DataPoint Un-verified.	Riley King (b) (4) (b) (4)	01 Apr 2021 19:21:40
Coding entries removed.	Riley King (b) (4) (b) (4)	01 Apr 2021 19:21:40
User entered 'HEPARIN lock' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	01 Apr 2021 19:21:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:21
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
Data point term sent to Coder	System	22 Mar 2021 22:38:57
User entered 'heparin'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:11:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Un-verified.	Riley King (b) (4)	01 Apr 2021 19:22:15
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 19:22:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Yes (Y)'	Riley King (b) (4)	22 Mar 2021 22:38:41
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:11:25
User closed query 'use of heparin in this instance is for heparin lock (to keep IV open) per hosp record' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:10:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
Query 'use of heparin in this instance is for heparin lock (to keep IV open) per hosp record' answered with 'reconciled ' (Site from CRA).	(b) (4)	
User entered 'TV patency' reason for change: Data Entry Error	Riley King (b) (4)	01 Apr 2021 19:22:24
DataPoint Un-verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:19:02
User opened query 'use of heparin in this instance is for heparin lock (to keep IV open) per hosp record' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'deep vein thrombosis prophylaxis'	(b) (4), (b) (6)	29 Mar 2021 17:12:33
	(b) (4)	
	Riley King (b) (4)	22 Mar 2021 22:38:41
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '500'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Other (OTHER)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'units'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'once (ONCE)'	Riley King (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User entered empty.	System	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User entered empty.	System	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:16
User entered empty.	System	22 Mar 2021 22:38:41

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:51
	(b) (4)	
User closed query 'Per CDM CLR Re-query: Per response kindly update the dose (5/325) in the dose field and also update the unit.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:05:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:54:18
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:54:18
Query 'Per CDM CLR Re-query: Per response kindly update the dose (5/325) in the dose field and also update the unit.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4) (b) (4)	15 Apr 2021 14:14:12
Data point term sent to Coder	System	15 Apr 2021 14:14:01
DataPoint Un-verified.	marissa Mueller (b) (4) (b) (4)	15 Apr 2021 14:13:56
	(b) (4)	
Coding entries removed.	marissa Mueller (b) (4) (b) (4)	15 Apr 2021 14:13:56
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4) (b) (4)	15 Apr 2021 14:13:56
User entered 'PERCOCET' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	15 Apr 2021 14:13:56
User opened query 'Per CDM CLR Re-query: Per response kindly update the dose (5/325) in the dose field and also update the unit.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 07:39:17

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and remove the extraneous information (i.e. 5/325) from the medication name field as this should be recorded in the Dose field. Kindly also update the Unit to reflect in milligram. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Troy Holdeman (b) (4)	15 Apr 2021 07:39:17 02 Apr 2021 20:26:43
Query 'Per DM CLR: Please review and remove the extraneous information (i.e. 5/325) from the medication name field as this should be recorded in the Dose field. Kindly also update the Unit to reflect in milligram. ' answered with 'Please clarify which you want. We were previously queried for recording combo medications with dosage in the dose instead of the name. ' (Site from DM).	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 19:24:10
User opened query 'Per DM CLR: Please review and remove the extraneous information (i.e. 5/325) from the medication name field as this should be recorded in the Dose field. Kindly also update the Unit to reflect in milligram. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:39:42
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:17:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 10:17:31
Data point term sent to Coder	System	22 Mar 2021 22:39:58
User entered 'Percocet(5/325)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'pain generalized'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:51
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	15 Apr 2021 14:13:56
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	15 Apr 2021 14:13:56
	(b) (4)	
User entered '5/325' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Apr 2021 14:13:56
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '1'	Riley King (b) (4)	22 Mar 2021 22:39:27
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:51
	(b) (4)	
DataPoint Un-verified.	marissa Mueller (b) (4)	15 Apr 2021 14:13:56
	(b) (4)	
Signature has been broken.	marissa Mueller (b) (4)	15 Apr 2021 14:13:56
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	marissa Mueller (b) (4)	15 Apr 2021 14:13:56
	(b) (4)	
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'tablet (TABLET)'	Riley King (b) (4)	22 Mar 2021 22:39:27
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'as needed (PRN)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Oral (ORAL)'	Riley King (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User entered empty.	System	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User entered empty.	System	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:10
User entered empty.	System	22 Mar 2021 22:39:27

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
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 Mar 2021 09:21:50
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 09:21:50
Data point term sent to Coder	System	22 Mar 2021 22:40:59
User entered 'morphine'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'pain generalized'	Riley King (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '2'	Riley King (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'as needed (PRN)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User entered empty.	System	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User entered empty.	System	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:27
User entered empty.	System	22 Mar 2021 22:40:03

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:51:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN HYDROCHLORIDE, PRODUCTSYNONYM: DITROPAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 22:41:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 22:41:55
Data point term sent to Coder	System	22 Mar 2021 22:40:59
User entered 'Ditropan'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'worsening of recurrent nephrolithiasis'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '5'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'mg (mg)'	Riley King (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'as needed (PRN)'	Riley King (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'Oral (ORAL)'	Riley King (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered empty.	Riley King (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '0'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:17:26
User entered 'No (N)'	Riley King (b) (4) (b) (4)	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User entered empty.	System	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User entered empty.	System	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:30
User entered empty.	System	22 Mar 2021 22:40:44

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:08:30
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:08:30
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
Data point term sent to Coder	System	01 Apr 2021 19:07:41
User entered 'Zofran'	Riley King (b) (4) (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	Riley King (b) (4) (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 19:06:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	01 Apr 2021 19:05:12
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Mar 2021 19:29:54
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Nausea- generalized'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered '4'	Riley King (b) (4)	01 Apr 2021 19:06:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	01 Apr 2021 19:05:12
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Mar 2021 19:29:54
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:37
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	01 Apr 2021 19:06:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	01 Apr 2021 19:05:12
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Mar 2021 19:29:54
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:40
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered empty.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:42
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'once (ONCE)'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:44
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered empty.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:46
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'Other (OTHER)'	Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:48
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'sublingually'	Riley King (b) (4)	01 Apr 2021 19:06:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	01 Apr 2021 19:05:12
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Mar 2021 19:29:54
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '3 Nov 2020'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:52
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '0'	(b) (4) Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	(b) (4) Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 19:06:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Riley King (b) (4)	01 Apr 2021 19:05:12
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Mar 2021 19:29:54
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:56
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '3 Nov 2020'	Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:59
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	Riley King (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	Riley King (b) (4) (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	Riley King (b) (4) (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:06:40
DataPoint activated with code reason code Data required.	Riley King (b) (4) (b) (4)	01 Apr 2021 19:05:12
DataPoint inactivated with code reason code Data not required.	Sherry Henning (b) (4) (b) (4)	23 Mar 2021 19:29:54

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 19:33:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 19:33:40
Data point term sent to Coder	System	07 Apr 2021 19:33:24
Coding entries removed.	marissa Mueller (b) (4) (b) (4)	07 Apr 2021 19:33:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:05:28
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:26:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 19:29:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 19:29:06
Data point term sent to Coder	System	01 Apr 2021 19:28:17
User entered 'dilaudid'	Riley King (b) (4) (b) (4)	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:05:31
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 19:28:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:05:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'pain- generalized'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:05:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '0.5'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:05:50
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'mg (mg)'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:05:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered empty.	Riley King (b) (4)	01 Apr 2021 19:28:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:05:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'once (ONCE)'	Riley King (b) (4)	01 Apr 2021 19:28:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:05:57
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered empty.	Riley King (b) (4)	01 Apr 2021 19:28:08
	(b) (4)	

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 19:55:29
User closed query 'please verify as IV per source' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:55:27
Signature has been broken.	marissa Mueller (b) (4)	07 Apr 2021 19:33:16
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	marissa Mueller (b) (4)	07 Apr 2021 19:33:16
	(b) (4)	
Query 'please verify as IV per source' answered with 'see source page' (Site from CRA).	marissa Mueller (b) (4)	06 Apr 2021 17:02:31
	(b) (4)	
User opened query 'please verify as IV per source' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:05:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Riley King (b) (4)	01 Apr 2021 19:28:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered empty.	Riley King (b) (4)	01 Apr 2021 19:28:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:07
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered '3 Nov 2020'	Riley King (b) (4)	01 Apr 2021 19:28:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:13
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:15
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:18
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered '3 Nov 2020'	(b) (4) Riley King (b) (4) (b) (4)	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:06:20
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	01 Apr 2021 19:28:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
User entered empty.	System	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
User entered empty.	System	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 14:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:40:21
User entered empty.	System	01 Apr 2021 19:28:08

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:59:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Nov 2020 14:29:40
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	24 Sep 2020 20:33:09
User entered 'No (N)'	(b) (4) marissa Mueller (b) (4)	01 Sep 2020 20:02:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:09:11
User entered '09 Sep 2020'	marissa Mueller (b) (4) (b) (4)	24 Sep 2020 20:34:03

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 16:10:09
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 17:12:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:11
User entered 'right ureteroscopy with laser lithotripsy'	marissa Mueller (b) (4)	24 Sep 2020 20:34:03
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:09:11
User entered 'Adverse Event (AE)'	marissa Mueller (b) (4)	24 Sep 2020 20:34:03
	(b) (4)	

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:59:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:21
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:11
User entered empty.	marissa Mueller (b) (4)	24 Sep 2020 20:34:03
	(b) (4)	

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:10:36
User entered '09 Sep 2020'	Jeri King (b) (4)	20 Oct 2020 20:57:49

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:10:37
User entered 'Placement of rental stent'	Jeri King (b) (4)	20 Oct 2020 20:57:49

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:10:40
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	20 Oct 2020 20:57:49

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:59:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:45
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:10:43
User entered empty.	Jeri King (b) (4)	20 Oct 2020 20:57:49

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:59:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	22 Oct 2020 16:12:27
Query 'please verify as 9Sep2020 as per hosp record' canceled (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:12:25
User opened query 'please verify as 9Sep2020 as per hosp record' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:12:01
User entered '07 Sep 2020'	Jeri King (b) (4)	20 Oct 2020 20:58:11

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:12:29
User entered 'CT abdomen/pelvis with contrast'	Jeri King (b) (4)	20 Oct 2020 20:58:11

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:14:49
User entered 'Adverse Event (AE)'	Jeri King (b) (4)	20 Oct 2020 20:58:11

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:59:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:12:39
User entered empty.	Jeri King (b) (4)	20 Oct 2020 20:58:11

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:59:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:35:17
User entered '03 Nov 2020'	Riley King (b) (4)	27 Jan 2021 20:29:25

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:35:17
User entered 'Ureteral stent'	Riley King (b) (4)	27 Jan 2021 20:29:25

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	18 Mar 2021 15:35:17
User entered 'Adverse Event (AE)'	Riley King (b) (4)	27 Jan 2021 20:29:25

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:59:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:51
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:35:17
User entered empty.	Riley King (b) (4)	27 Jan 2021 20:29:25
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:59:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:35:17
User entered '3 Nov 2020'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:30:06

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:35:17
User entered 'Lithotripsy'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:30:06

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:35:17
User entered 'Adverse Event (AE)'	Riley King (b) (4) (b) (4)	27 Jan 2021 20:30:06

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:59:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:53
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:35:17
User entered empty.	Riley King (b) (4)	27 Jan 2021 20:30:06
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:59:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	18 Mar 2021 15:35:17
User entered '10 Dec 2020'	Riley King (b) (4)	27 Jan 2021 20:30:34

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:35:17
User entered 'Percutaneous nephrolithotomy'	Riley King (b) (4)	27 Jan 2021 20:30:34

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	18 Mar 2021 15:35:17
User entered 'Adverse Event (AE)'	Riley King (b) (4)	27 Jan 2021 20:30:34

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 14:59:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:21:55
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
DataPoint Verified.	(b) (4)	18 Mar 2021 15:35:17
User entered empty.	Riley King (b) (4)	27 Jan 2021 20:30:34

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:59:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '21 Apr 2021'	Riley King (b) (4)	23 Apr 2021 16:02:59
	(b) (4)	

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'lithotripsy'	Riley King (b) (4)	23 Apr 2021 16:02:59
	(b) (4)	

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'Adverse Event (AE)'	Riley King (b) (4)	23 Apr 2021 16:02:59
	(b) (4)	

US3062079

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:59:21

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered empty.	Riley King (b) (4)	23 Apr 2021 16:02:59
	(b) (4)	

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered	System	12 Sep 2020 21:14:44
'USA-US090-2020-MRNA-1273-P301000001'		

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Richard'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Glover'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '700 Medical Center Dr.'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Newton'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'KS'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '67114'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:40:31
User entered 'US' (non-conformant).	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Oct 2020 18:17:14
User entered '3'	System	15 Oct 2020 13:05:10
User entered '2'	System	25 Sep 2020 12:46:06
User entered '1'	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered	System	12 Sep 2020 21:14:44
'USA-US090-2020-MRNA-1273-P301000001'		

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Richard'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Glover'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '700 Medical Center Dr.'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Newton'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'KS'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '67114'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:40:31
User entered 'US' (non-conformant).	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Oct 2020 18:17:14
User entered '3'	System	15 Oct 2020 13:05:10
User entered '2'	System	25 Sep 2020 12:46:06
User entered '1'	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
User entered '12/Sep/2020 17:15'	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:21

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.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
User entered 'I'	(b) (4), (b) (6)	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered	System	12 Sep 2020 21:14:44
'USA-US090-2020-MRNA-1273-P301000001'		

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Richard'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Glover'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '700 Medical Center Dr.'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Newton'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'KS'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '67114'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:40:31
User entered 'US' (non-conformant).	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Oct 2020 18:17:14
User entered '3'	System	15 Oct 2020 13:05:10
User entered '2'	System	25 Sep 2020 12:46:06
User entered '1'	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
User entered '25/Sep/2020 08:46'	System	25 Sep 2020 12:46:06

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:21

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.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:04:58
DataPoint Verified.		08 Oct 2020 16:12:36
User entered 'I'		25 Sep 2020 12:46:06

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered	System	12 Sep 2020 21:14:44
'USA-US090-2020-MRNA-1273-P301000001'		

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Richard'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Glover'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '700 Medical Center Dr.'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Newton'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'KS'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '67114'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:40:31
User entered 'US' (non-conformant).	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Oct 2020 18:17:14
User entered '3'	System	15 Oct 2020 13:05:10
User entered '2'	System	25 Sep 2020 12:46:06
User entered '1'	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:48:08
User entered '15/Oct/2020 09:05'	System	15 Oct 2020 13:05:10

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:21

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.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:48:09
Reviewed for Safety.		21 Oct 2020 18:16:57
User entered 'I'		15 Oct 2020 13:05:10

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered	System	12 Sep 2020 21:14:44
'USA-US090-2020-MRNA-1273-P301000001'		

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Death

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'Yes (Y)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 21:15:13
User entered 'No (N)'	System	12 Sep 2020 21:14:44

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Richard'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Glover'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '700 Medical Center Dr.'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'Newton'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered 'KS'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: User entered '67114'	System	14 Sep 2020 21:43:48

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:12:36
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 12:45:44
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:40:31
User entered 'US' (non-conformant).	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	21 Oct 2020 18:17:14
User entered '3'	System	15 Oct 2020 13:05:10
User entered '2'	System	25 Sep 2020 12:46:06
User entered '1'	System	12 Sep 2020 21:15:18

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:47:49
User entered '21/Oct/2020 18:17'	System	21 Oct 2020 18:17:14

US3062079

Folder: SAE USA-US090-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:59:21

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.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 14:47:47
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 18:17:14

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered	System	28 Jan 2021 19:02:44
'USA-US090-2021-MRNA-1273-P301000007'		

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Richard'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Glover'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '700 Medical Center Dr.'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Newton'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'KS'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '67114'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'US'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:40:45
User entered '5'	System	02 Apr 2021 17:00:32
User entered '4'	System	23 Mar 2021 13:45:45
User entered '3'	System	02 Mar 2021 15:52:03
User entered '2'	System	11 Feb 2021 16:08:35
User entered '1'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered	System	28 Jan 2021 19:02:44
'USA-US090-2021-MRNA-1273-P301000007'		

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Richard'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Glover'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '700 Medical Center Dr.'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Newton'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'KS'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '67114'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'US'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:40:45
User entered '5'	System	02 Apr 2021 17:00:32
User entered '4'	System	23 Mar 2021 13:45:45
User entered '3'	System	02 Mar 2021 15:52:03
User entered '2'	System	11 Feb 2021 16:08:35
User entered '1'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
User entered '28/Jan/2021 14:03'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:21

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.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered	System	28 Jan 2021 19:02:44
'USA-US090-2021-MRNA-1273-P301000007'		

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Richard'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Glover'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '700 Medical Center Dr.'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Newton'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'KS'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '67114'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'US'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:40:45
User entered '5'	System	02 Apr 2021 17:00:32
User entered '4'	System	23 Mar 2021 13:45:45
User entered '3'	System	02 Mar 2021 15:52:03
User entered '2'	System	11 Feb 2021 16:08:35
User entered '1'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
User entered '11/Feb/2021 10:08'	System	11 Feb 2021 16:08:35

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:59:21

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.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:51:50
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 16:08:35

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered	System	28 Jan 2021 19:02:44
'USA-US090-2021-MRNA-1273-P301000007'		

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Richard'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Glover'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '700 Medical Center Dr.'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Newton'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'KS'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '67114'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'US'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:40:45
User entered '5'	System	02 Apr 2021 17:00:32
User entered '4'	System	23 Mar 2021 13:45:45
User entered '3'	System	02 Mar 2021 15:52:03
User entered '2'	System	11 Feb 2021 16:08:35
User entered '1'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
User entered '02/Mar/2021 10:52'	System	02 Mar 2021 15:52:03

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:59:21

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.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 17:00:01
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 15:52:03

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered	System	28 Jan 2021 19:02:44
'USA-US090-2021-MRNA-1273-P301000007'		

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Richard'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Glover'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '700 Medical Center Dr.'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Newton'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'KS'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '67114'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'US'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:40:45
User entered '5'	System	02 Apr 2021 17:00:32
User entered '4'	System	23 Mar 2021 13:45:45
User entered '3'	System	02 Mar 2021 15:52:03
User entered '2'	System	11 Feb 2021 16:08:35
User entered '1'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered '23/Mar/2021 06:45'	System	23 Mar 2021 13:45:45

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:59:21

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.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 17:00:01
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 13:45:45

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered		28 Jan 2021 19:02:44
'USA-US090-2021-MRNA-1273-P301000007'	System	

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Richard'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Glover'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '700 Medical Center Dr.'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Newton'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'KS'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '67114'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'US'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:40:45
User entered '5'	System	02 Apr 2021 17:00:32
User entered '4'	System	23 Mar 2021 13:45:45
User entered '3'	System	02 Mar 2021 15:52:03
User entered '2'	System	11 Feb 2021 16:08:35
User entered '1'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
User entered '02/Apr/2021 13:00'	System	02 Apr 2021 17:00:32

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:59:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:00:32

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered	System	28 Jan 2021 19:02:44
'USA-US090-2021-MRNA-1273-P301000007'		

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 13:40:29
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:20:05
	(b) (4)	
User entered 'Yes (Y)'	System	08 Apr 2021 18:58:55
Un-reviewed for Safety.	System	08 Apr 2021 15:19:12
DataPoint Un-verified.	System	08 Apr 2021 15:19:12
Signature has been broken.	System	08 Apr 2021 15:19:12
User entered 'No (N)'	System	08 Apr 2021 15:19:12
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Yes (Y)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'No (N)'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Richard'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Glover'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '700 Medical Center Dr.'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'Newton'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'KS'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered '67114'	System	28 Jan 2021 19:02:44

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:37:06
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:03:20
User entered 'US'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Apr 2021 13:40:45
User entered '5'	System	02 Apr 2021 17:00:32
User entered '4'	System	23 Mar 2021 13:45:45
User entered '3'	System	02 Mar 2021 15:52:03
User entered '2'	System	11 Feb 2021 16:08:35
User entered '1'	System	28 Jan 2021 19:03:15

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	16 Apr 2021 15:18:51
	(b) (4)	
User entered '09/Apr/2021 13:40'	System	09 Apr 2021 13:40:45

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:59:21

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.	Richard Glover (b) (4)	16 Apr 2021 15:18:51
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 13:40:45

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'USA-US090-2021-MRNA-1273-P301000012'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Yes (Y)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Yes (Y)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Richard'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Glover'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered '700 Medical Center Dr.'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Newton'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'KS'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered '67114'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'US'	System	26 Apr 2021 14:01:17

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 14:01:17

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'USA-US090-2021-MRNA-1273-P301000012'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Yes (Y)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Yes (Y)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'No (N)'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Richard'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Glover'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered '700 Medical Center Dr.'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'Newton'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered 'KS'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 14:01:04
User entered '67114'	System	26 Apr 2021 14:00:38

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'US'	System	26 Apr 2021 14:01:17

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 14:01:17

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered '26/Apr/2021 10:01'	System	26 Apr 2021 14:01:17

US3062079

Folder: SAE USA-US090-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:59:21

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.	Richard Glover (b) (4)	28 Apr 2021 11:58:18
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 14:01:17